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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. <<TEXT>>

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☐ *Additional inventors are being named on the <<TEXT>> separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

LOWER EXTREMITY PROSTHESIS REPLICATING FUNCTION OF HUMAN MUSCULATURE

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ENCLOSED APPLICATION PARTS ***(check all that apply)***

☒ Specification *Number of Pages* 30
☒ Drawing(s) *Number of Sheets* 41
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
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METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees

☐ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 01-2135

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.
☒ No
☐ Yes, the name of the U.S. Government agency and the Government contract number are:

[Page 1 of 1] Date 04/01/04

Respectfully submitted,

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Docket Number: 183.43731I.00

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

Artificial Muscle Form and Function

I. Design concept intro = problem 14% (long) -26% (short). Solution needed…windlass, human and prosthetic comparison.

   a. Energy

      i. PE

      ii. EE

      iii. KE = KP

      iv. KPower = PROPULSIVE Force

   b. Foot, ankle, calf, shank, ~~posterior artificial~~ ~~muscle~~. + VISCOELASTIC ~~PASSIVE~~ ASSIST DEVICE

   c. Artificial muscle = VISCOELASTIC PASSIVE DEVICE

   d. Increased PE = KE = $\frac{1}{2}mv^2$

      i. CAM post calf

      ii. Foot shell

      iii. Windlass

II. Artificial muscle = VISCOELASTIC PASSIVE DEVICE

   a. Max tension, max unloading.

      i. Mass, length, width, cross-sectional area

      ii.

   b. Form and function, monolithic and integral

      i. Strap solid

      ii. Fusiform

      iii. Bi-pinnate

      iv. Multi-pinnate

v. Combination of design

1. strap to muscle

c. Function

III. Cams, Pads, Bladders

a. Cams

i. Worm gear

ii. Bolt adjustment

iii. Sylinoid

b. Pads

i. Posterior calf

ii. Longitudinal arch

iii. Bladders

1. Calf

IV. Foot Shell

V. Claims

Background and Field of Invention

VISCOELASTIC + A LEAF SPRING DEVICE

Our invention is a device that replicates the function of human musculature. A device that adds potential energy to a prosthetic system which results in an increase in the prosthetic systems kinetic power generation potential. Wherein, the increase in kinetic power generation can be manipulated by the user to facilitate functional outcomes as required by the users activities.

13281 U.S. PTO 040104

I. Design Concept – Background, Intro

The prosthesis as shown in our high performance foot patent # US6,562,075 as represented by figures ~~#~~ 1, + 2, ~~X~~, ~~and~~ ~~X~~ have been pathokinesiology (GAITTESTED) ~~GAITTESTED~~ ~~tested~~ (3D motion analyzed) on two unilateral transtibial amputees at Stanford University and the University of Southern California (USC). The test results indicate see figures 3 & 11 (jack KP) that the prosthesis does not produce equal amounts of ankle joint sagittal plane kinetic power as compared to the unaffected side ~~limb~~ creating inequalities in gait. This Figure 3 (jack KP) shows that a 14% gap exists between the prosthetic ankle joint sagittal plane kinetic power and his unaffected "normal" side. Fig 4 (average KP) indicates that the average of two subjects prosthetic side sagittal plane ankle joint kinetic power wherein one subject had an 8" inch long calf shank ~~fig # ___~~ and the other test subject had a 4" long calf shank ~~as shown in figure 3 #~~ This figure indicates that a 26% gap exists between "normal" unaffected and affected (prosthetic side) ankle joint sagittal plane kinetic power. This sagittal plane ankle joint kinetic power generation has been identified as the propulsive force needed to propel the trailing limb and body forward for the next step.

The scientific literature suggests that even though all prior art prosthetic feet have varied mechanical designs they all function (in creating sagittal plane ankle joint power) about the same. For example, US patent # ___ (Seattle Lite Foot) and Safe Foot US patent # 5,066,305 create approximately 25% of "normal" ankle joint sagittal plane kinetic power. This represents a 7~~6~~5% gap between the affected and unaffected sides. ~~The problem of generating "normal" human ankle joint sagittal plane kinetic power with a prosthetic foot, ankle, and calf...?~~

Van Phillips US patent # 4,547,913 shows a prior art prosthetic foot, ankle, and calf wherein the calf and ankle are monolithically formed. This patent represents one of the first attempts to include an elastic energy storage system at the calf shank level. This particular prosthetic design configuration has been re-invented by patents 5,514,185, ____, ____, ____, ____, ____, ____, ____.

US 5,509,938
US 5,299,319
US 6,527,811 B1
US 5,976,191
US 5,181,933
US 5,387,246
US 6,406,500

5,776,205
6,071,313
5,944,760
US 6,241,776 B1
US 6,280,479
US PUBLICATION # US 2003/0191541 A
US 6,602,295 B1
5,899,944
5,181,932
5,593,457
5,486,209
US PUBLICATION US 2003/0093158 A1
" " US 2003/0120354 A1
" " US 2002/0077706 A1

The ankle joints sagittal plane kinetic power generation potential in these designs is significantly and deficiently affected. Figure 5 (Jacks TPA and Flex) shows a unilateral transtibial amputee who wore in separate gait trials a Van Phillips patent # 5,514,185 foot and our foot figure 1. The difference in prosthetic ankle joint sagittal plane kinetic power generation indicates that our prosthetic design generates approximately 143% more power.

The 14% gap in ankle joint sagittal plane kinetic power generation that exists between our prosthetic foot system and the human foot and ankle system can be bridged by adding a posterior ~~calf~~ viscoelastic, or a leafspring device that adds potential and elastic energy storage capacity to our prosthetic system.

Design Concept

Through the proper application of mechanical design a prosthetic structure, in this case a foot, ankle, calf, and posterior ~~artificial muscle design~~ viscoelastic or leafspring devices, has been created, which for the first time efficiently transforms potential elastic stored energy into kinetic energy and measurably improves the terminal stance phase propulsive force, at the

ankle, allowing for normalized advancement of the trailing limb and forward movement during amputee gait.

Design Theory

The foundation for the Phase I prototype designs (P1 and P2 - both of which incorporate a resilient longitudinal foot keel, rigid ankle coupler, resilient anterior facing convexly curved parabolic calf shank, and posterior shank viscoelastic ~~calf artificial muscle~~ device) were the mechanical structures of the human foot, ankle, and calf and their respective responses to ground reaction force throughout the stance phase of gait. By better understanding the biomechanical processes in the human foot, ankle, and calf we believe that we can create a lower extremity prosthesis, which is purely mechanical, that will be capable of replicating normal human function.

Over the past 5 years our Phase I prototypes have evolved to achieve an accurate representation of the known biomechanical processes, as they occur in human gait.

The primary focus of the design is to use resilient structures that have the capacity to store elastic energy which can be transformed into kinetic energy. This mechanical energy concept was taken one step further by creating a posterior ~~calf~~ shank viscoelastic + or leafspring ~~artificial muscle~~ device which has the capability of storing its own potential energy, wherein the potential energy is created by the work required to load the muscle device with energy. A simple illustration, conceptually, of potential and kinetic energy can be explained by the stretch and release of a rubber band. When the rubber band is stretched it stores potential energy via its elasticity and when the rubber band is released the elastic stored energy is transformed into kinetic energy or the contraction

ELASTIC ENERGY STORAGE CAPACITIES

of the rubber band. This same principle applies to the ~~capacity~~ of the resilient longitudinal foot keel and parabolic ~~calf~~ shank. In the stance phase of gait mechanical energy is created by the multi-segment system. This mechanical energy through the gait cycle creates potential energy by "loading" the Resilient ~~elastic~~ ~~calf~~ shank and foot keel. The stored elastic ~~potential~~ energy is released/transformed via the mechanical structures of the Phase I prototype into kinetic energy which is transformed to kinetic power + creates a propulsive force. Moreover, during gait, the body's center of gravity rises and falls creating potential and kinetic energy, respectively. These alternating energy events contribute to the efficiency of human locomotion, through the cyclic nature of energy absorption and generation, and enhance the loading properties of the elastic prosthetic foot.

The second major design theory incorporates a variable geometric mechanical design concept, wherein, through the orchestration of one radius next to another, wherein, the radii orientation are manipulated in the sagittal, frontal and transverse planes. This radii orchestration was further developed by arranging the radii to respond to a single ground reaction force by compressing and/or expanding. This compression and/or expansion of the radius relates directly to the angular velocity of the resilient structure going down or up respectively. Further development of this radii concept includes that the angular velocity potential is a function of the radius size and is a function of the distance from a point of rotation. A larger radius has greater angular velocity potential. → put in new analysis → multi segment → attachment (A)

Our current prosthetic system which includes a resilient foot, ~~ankle~~, and ~~calf~~ shank needs a boost of potential energy. Herein, lies our patent. A posterior and/or dorsal device and/or devices that not only adds potential energy but increases the

elastic energy storage capacity of the whole system. Wherein, each separate component, i.e. the longitudinal foot keel ~~calf~~ shank posterior or dorsal device contributes a percentage to the total kinetic power generation value. (Our invention is to replicate the function of the human posterior calf musculature and the windlass action of the foot. Campbell Childs, US Patent #, achieved this foot windlass effect, however, our windlass design is more simplistic and effective with increased elastic energy storage capacity. ~~Ron I don't know if a patent subcategory exists on this subject. I also don't know of a prior art invention that incorporates the multitude of designs embodied in this provisional patent.)~~

The posterior ~~calf~~ shank device could be a ~~simple~~ single leaf spring figure 6 + OR MULTIPLE LEAF SPRINGS AS SHOWN IN FIGURE 7 with rigid and/or (elastic/resilient) strap. Or it could be an visco elastic artificial muscle representation, Figures 8+9. The artificial ~~muscle~~ VISCOELASTIC DEVICE could include a simple solid elastic strap (figure) 10 and/or multiple layers of straps. However, its form characteristics dictating specific motion characteristics. The ~~artificial muscle~~ VISCOELASTIC DEVICE further including a device ~~[illegible]~~ #1 that adds potential energy by pre-stretching and/or pre-loading the ~~artificial muscle~~ VISCOELASTIC DEVICE with potential energy. This ~~posterior~~ shank device #1 could be a pad, figure 11, and/or pads, figure 12, of different thicknesses, or it could be an air or hydraulic bladder, figure 13, or it could be a cam, figure 14, wherein, the user of the prosthesis manipulates the device #1 to increase and/or decrease the amount of potential energy added to the prosthetic system. Our prosthetic foot shell incorporates an elastic strap system that originates in the posterior plantar and inserts in the anterior plantar regions of a foot shell. FIG 15 This elastic plantar foot system is not limited to being part of a foot shell system. It can be attached to the posterior and anterior ends of our longitudinal foot keel. FIG 16 + 17 This elastic windlass system will increase the

elastic energy storage capacity of our foot keel system which when added to our prosthetic system will increase our elastic energy storage capacity. This elastic energy will be transformed into increased kinetic power.

Our elastic windlass foot system can be manipulated by the user to increase and/or decrease the amount of potential energy. This manipulation is achieved by a longitudinal arch pad system of various thicknesses and forms. FIG 18 Each form/shape dictating a pre-determined stretch on the windlass system. In use the user can change the longitudinal pad to a thicker, thinner, wider, and/or narrower form, wherein a thicker longitudinal arch pad increases the length by stretching/preloading the windlass elastic material.

The need exists for device #1 and the windlass system because as the users activity level increases the prosthetic system should be able to be manipulated by the user to increase and/or decrease the kinetic power generation. This will allow our prosthesis to be utilized by the amputee for a wide variety of activities including walking, running, and jumping.

VISCOELASTIC DEVICE

II. ~~Artificial Muscle~~ Section

Human muscles exhibits specific form and function characteristics. These form function characteristics can be simulated with a viscoelastic prostheses. For example, a muscle can be fusiform and/or multi-pinnate formed each dictating different functional motion outcomes. A muscles mass as represented by a cross sectional area times length dictates its power potential. A larger muscle mass will create an increase in power potential. Two muscles of equal mass that are either have long and narrower cross-section, figure 10A, ~~or~~ or short and larger cross sectional areas FIG 10B will create different motion outcomes. ~~(FSS)~~ FIG 19 A. For example, a long and narrow cross sectional area muscle has

increase range of motion potential as compared to a short large cross sectional muscle. FIG 19B A short and large cross sectional muscle of the same mass creates greater tension values in a shorter time frame. However, a long narrow muscle has greater unloading potential. In human walking the posterior calf muscle group in response to A ground reaction force loads eccentrically and an eccentrically contracting muscle has increased tension capabilities. Therefore a short wider cross sectional area muscle will replicate this function better than a long narrow muscle of the same mass. Different muscle configurations can be layered one on top of another creating many different motion outcomes. Each motion outcome potential having range of motion tension, unloading and timing characteristics.

Move this sentence

Our patent creates a prosthetic ~~artificial muscle~~ VISCOELASTIC + RESILIENT STRUCTURE based on these simple biomechanical functions. Our ~~artificial muscles~~ VISCOELASTIC ~~RESILIENT ARTIFICIAL~~ DEVICES are generally monolithically formed out of an elastic material such as rubber, however, anybody skilled in the art would know that elastic materials other than rubber could be utilized and that varying densities and durometers could be employed in the manufacture of ~~our muscles~~ VISCOELASTIC DEVICES. Our ~~muscles~~ VISCOELASTIC DEVICE could also be a biomechanical elastic structure incorporating resilin at the top end of the elastic spring efficiency scale. A hybrid of biological and mechanical forms. Our ~~muscles~~ VISCOELASTIC DEVICES can be integrally formed. Wherein, a material with different and/or the same elastic rating can be attached to the terminal ends wherein different mechanical forms are fastened together. Each ~~artificial muscle~~ VISCOELASTIC DEVICE having two terminal ends usually a proximal and distal orientation, however, as in the human they could be oriented medial to lateral and/or anterior to posterior or any combination thereof.

Our ~~muscles~~ VISCOELASTIC DEVICES can be manufactured by injection molding, machining or any combination thereof. Our ~~muscle~~ VISCOELASTIC forms can be a simple elastic strap FIG 10A where in the cross sectional area and length can be varied to achieve different functional motion outcomes. The length can be varied to achieve different functional motion outcomes. The length to cross sectional area of the muscle dictating specific elastic storage capacity, max tension, max unloading and power potential. NOT Our ~~muscles~~ VISCOELASTIC DEVICES can be solid, fusiform, bi-pinnate and/or multi-pinnate formed with each ~~muscle~~ VISCOELASTIC DEVICE configuration dictating specific motion outcomes. FIG 8 A-D + FIG 9 A-E Our ~~muscles~~ VISCOELASTIC DEVICES can be single and/or multilayered. Our ~~muscles~~ VISCOELASTIC DEVICE can be a combination of ~~muscle~~ VISCOELASTIC and/or ~~strap~~ NON ELASTIC or any combination thereof. Our ~~muscles~~ VISCOELASTIC elastic energy storage capacity being derived from the elastic properties of the material in the ~~muscles~~ VISCOELASTIC DEVICES are made of and its mass. Our ~~muscles~~ VISCOELASTIC form and mass dictate specific motion outcomes. Our ~~muscles~~ VISCOELASTIC DEVICES can be attached to the proximal end of our calf shank, below knee prosthetic socket, and/or thigh cuff on any combination thereof. Our ~~muscles~~ VISCOELASTIC DEVICES distal attachment could be the distal end of the ~~calf~~ shank, posterior 1/3rd of the foot keel, and/or foot keel or any combination thereof. Our ~~muscles~~ VISCOELASTIC DEVICES are not specifically meant for the foot, ankle, and ~~calf~~ shank but can be utilized at the hip knee, ankle, toes, elbow, wrist, fingers, shoulder, trunk, neck, eyes, ears, mouth, thumb, and/or any combination thereof. Our ~~prosthetic muscle~~ VISCOELASTIC DEVICES can be cross sectional shaped as a: FIG 9A + FIGURE A22 rectangle, square, oblong, flat, round, triangular, or any poly angular structure, and tubular. The elongated shapes can be (see figures): FIG B 222 + FIG 9A-E

VISCOELASTIC DEVICES

Our ~~artificial muscles~~ ~~elastic and~~ form characteristics can be manipulated by design form to replicate the function of any muscle in the human body. Wherein every human muscle has a specific motion and function capability. Our ~~muscles~~ VISCOELASTIC DEVICES can be a hybrid of bio-mechanical forms wherein biological tissues are interfused with mechanical elements to create structures capable of contracting, i.e. shortening with electrical input. Our ~~muscles~~ VISCOELASTIC DEVICE can be a hybrid of elastic mechanical elements capable of responding to an electrical stimulus wherein the electrical stimulus makes the mechanical elements shorten in length causing a shortening of the ~~muscles~~ VISCOELASTIC DEVICE ~~length~~. Our ~~muscles~~ VISCOELASTIC DEVICES are beyond simple synthetic rubber.

(Our prosthetic foot keel and calf shank resilient – all) WHAT ?

The design of our ~~muscles~~ VISCOELASTIC DEVICES terminal ends can be integral or monolithically formed with the body and/or central region. The terminal end can have a male or female dove-tail wherein the opposite design is integrally or monolithically formed to its mate (See figure 20 A, B + C). The dove-tail can be oriented to be at 90° to 0°. The mate to the ~~muscle~~ VISCOELASTIC DEVICE terminal end can be made of an alloy, rubber, plastic or any combination thereof. The terminal end of our muscle can be formed with an elastic and/or non-elastic material (see figure 20 C). Our ~~muscles~~ VISCOELASTIC terminal end can have a length adjustment fastener attachment wherein the muscle can be tensioned by shortening the over all length of the ~~muscle~~ VISCOELASTIC DEVICE (see figure 21, 6+7 ___). Our ~~muscles~~ VISCOELASTIC DEVICE terminal ends can be any combination of the aforementioned designs. Our ~~muscles~~ VISCOELASTIC can be made of a fibrous elastic element that can be expanded to produce movements for the joints they cross and/or for the human structure they are intended to mimic. Our ~~muscles~~ VISCOELASTIC DEVICE can be ....brainstorm here_____.

VISCOELASTIC-TOR
~~Artificial muscle~~ resilient leaf spring design, see figure 21A, this ~~muscle~~ LEAF SPRING design incorporates a single and/or multiple leaf springs. The leaf springs can be made of rubber, plastic, alloy and/or composite the resiliency of the material and form dictating its functional motion outcomes. The leaf spring can be single and/or multilayered and they can be of the same and/or different lengths. The general shape of the leaf spring is curvilinear with a straight section and/or curvilinear throughout. The leaf springs can respond to a force by compressing and/or expanding. Our leaf springs can be made in a variety of lengths, they can be layered in multiple layers. The strap material for our leaf spring muscle can be single or multilayered. The strap can be non-stretching and/or stretchable. The function of our leaf spring ~~muscle~~ DEVICE is to replicate the function of a human muscle. Our leaf springs can be made of a resilient material and/or resilient materials or any combination thereof to facilitate the same and/or different spring rates. Our leaf springs can be monolithically and/or integrally formed. Our leaf spring can be fusiform, bi-pinnate, and/or multi-pinnate. Our leaf springs can be formed with a middle section single and/or multiple cutouts.

Our cutouts can be rectangular, square, triangular, poly angular, round/circular, half moon, crescent moon in shape ~~(See tab 2 with drawn shapes)~~. The leaf springs can be bar stock and/or non-bar stock in shape, see figure below ~~(m,n,o,p,q,r,s)~~. M N O P Q Q1 R S

Our leaf springs can have symmetry and/or asymmetrical form. Our leaf spring can have varied spring rates within the monolithic form, wherein, the spring rate can be

FIGURE R

softer and/or firmer depending on the curvilinear forms. For example (~~see drawing on 230~~). X+Y and A-C can be the same or different widths, the spring rate of each section of the leaf spring being related to the width and thickness of the leaf spring in (figure R ~~on 230~~) was the same from top to bottom, the width of X, Y, A, B, and C would dictate spring rates for that area of the structure. This varied width design allows a single structure to have varied spring rates wherein the spring rates can be firmer and/or softer. For example, X would be softer than Y, and C softer than B, and B softer than A. This allows us to create a varied spring rate with one structure. This varied spring rate can be appreciated by the amputee because of ~~on~~ varied force loading or ~~of~~ the prosthetic system which occurs during walking, running, and jumping activities, the spring rate would ramp up. The leaf spring below is an example. Figure S (~~233~~) section 1 would have less spring rate than section 2 and 3. As a consequence the small force loading section 1 would respond as the forces go up; sections 2 and 3 would be utilized giving us a mechanical structure that ramps up its spring rate proportional to its force load.

Another varied embodiment would be to have a leaf spring that has a raised middle section that would engage as force loading increases. For example T1-4 (~~234-236~~). This particular leaf spring design does not have to be rectilinear in form but could be curvilinear in form combining both curvilinear and/or rectilinear forms. Anybody skilled in the prior art would know that our basic design principles could be combined to achieve a desired motion outcome.

AN ~~Primary~~ objective of our prosthetic system/design is to have a foot keel, ankle, and shank that is highly flexible yet during the late mid-stance phase of gait the system becomes more rigid or when force loading goes up in running and jumping activities our structure becomes more rigid. This has been accomplished with our longitudinal foot keel and monolithically formed ankle and shank wherein the longitudinal arch area of the longitudinal foot keel and the parabolic shaped calf shank respond to the late mid-stance ground reaction force by expanding which increases the angular velocity potential of both structures which has proven to improve the ankle joints sagittal plane kinetic power generation value. The human ankle joint has two primary muscle groups which influence its ability to create torque and they are the anterior pretibial and posterior triceps surae muscle groups. The scientific literature suggests that an 11 to 1 torque ratio exists between these two muscle groups with the posterior group being 11. The biomechanical function of our ~~viscoelastic + composite~~ ~~posterior~~ device whether it be a leaf spring and/or muscle – viscoelastic device ~~artificial~~ ~~muscle~~ and/or windlass allows us to achieve this 11 to 1 posterior to anterior torque ratio. ANOTHER OBJECTIVE 1,000,000

By preloading our shank and foot keel with our windlass and ~~calf~~ shank, and/or ~~calf~~ shank and foot keel devices we can fabricate more flexible foot keel and ~~calf~~ shank units which are highly mobile yet become more rigid on force loading further replicating the human structures movement and motion characteristics.

III. Windlass foot shell (T~~HIS SHOULD BE AN ENTIRELY SEPARATE PROVISIONAL~~ P~~ATENT)~~ ~~SPAAH NO AT PRESENT.~~ Well Let Ron Decide.

Traditional cosmetic foot shells are simply cosmetic in nature not adding any degree of biomechanical function. Our windlass foot shell cover adds potential energy (PE) to the longitudinal foot keel, this increase in (PE), functions to increase the kinetic energy potential. Our windlass foot shell incorporates a single and/or multilayer of plantar elastic straps/bands which originate on the plantar surface posteriorly and insert on the plantar surface anteriorly. These elastic bands can be integrally and/or monolithically formed (see figure 15 ~~___~~). These plantar bands can be molded into the foot shell when the foot shell is manufactured, by injection molding (~~see figure ___~~). These plantar bands can be solid bands, fusiform, and/or multi-pinnate formed. Any combination thereof can be utilized in our windlass foot shell system. For example a solid band can be layered with a fusiform and/or multi-pinnate formed bands. By varying the elastic band forms varied motion outcomes are created. Our windlass effect is not limited to the foot shell system. It can be created by attaching the elastic plantar bands to the anterior and posterior ends of the longitudinal foot keel of our prosthetic system. These plantar bands anterior and posterior attachments can be fastened by a fastener ~~(oh really I would have never guessed – its all so clear!)~~ and/or slipped over the terminal ends of the longitudinal foot keel (~~see figures rivets and globs~~ FIG 16). Varied potential energy can be added to this system by the use of variable thickness longitudinal arch pads. Wherein, the user of the device would change the thickness the thickness of the longitudinal arch pad for higher or lower functioning activities such as walking, running, and jumping. For example, the user of our prosthetic system would use a thinner longitudinal arch pad for walking. When the user of our prosthetic system wants to run he/she would remove the thin longitudinal arch pad from their shoe and exchange it with

a thicker longitudinal arch pad: this thicker longitudinal arch pad would increase the tension on the plantar band. This increase in tension preload is accomplished because the longitudinal foot keel is more rigid than the plantar elastic bands and the distance the plantar elastic bands must travel from their terminal ends is larger. Therefore a thicker pad will increase the tension preload stretch on the plantar bands. In practice the user of our prosthetic system can add one and/or multipads to achieve a tension (preload) that suites their activity. A thicker longitudinal arch pad for increased activities.

IV. Cams, Pads, Bladders (Potential energy manipulating devices).

A device which functions to prestretch/preload or otherwise increase tension on our viscoelastic device ~~artificial muscle~~ is needed to allow the user of the prosthesis to add potential energy (PE) to his prosthetic system. An increase in P.E. will increase the kinetic energy which increases the propulsive force to propel the trailing limb and body forward for the next cycle. This cycle can be walking, running, and/or jumping activities. This preloading of our viscoelastic device ~~artificial muscle~~ and windlass bands also functions to increase the ratio of posterior to anterior ankle joint torque values.

11/12/18 These potential energy devices can be air bladders, cams, and/or pads. For example figure (____) shows several thicknesses of pads which can be utilized as previously discussed with our elastic bands an windlass device. Similar pads can be attached to the posterior and/or anterior aspect of a prosthetic device. For example figure (11) shows a pad added to the posterior aspect of a below knee socket. However, any one

skilled in the art would know that these pads could be used on the thigh, forearm, upper arm, hand, finger, neck, and/or any other prosthetic part to increase tension on our VISCOELASTIC ~~artificial muscle~~ device.

Air Bladders

Pneumatic and hydraulic bladders can also be used to increase tension on our windlass and VISCO ELASTIC ~~artificial muscle~~ devices For example figure (13) shows a pneumatic bladder which is attached to the posterior aspect of below knee socket wherein the bladder ~~is~~ WOULD BE sandwiched between the socket and VISCOELASTIC DEVICE ~~artificial muscles~~ and/or DEVICES. ~~muscles~~. In practice this pneumatic is inflated increasing the tension on our artificial muscles. This increase in tension preloading adds potential energy (PE) to our system. This (PE) is variable with a direct relationship to the volume of air and expansion of the device. To facilitate expansion of our air bladder in one direction for example the pneumatic bladder is encapsulated in a cloth sheath that has rigidity on the sides which is achieved by the weave and flexibility in the anterior and posterior direction for example. The cloth sheath can be made of Kevlar, composites, cotton, nylon, and/or synthetic materials. Our pneumatic bladder can also be formed monolithically wherein the medial and lateral sides of the bladder are made more rigid and thicker THAN ~~tan~~ the anterior and posterior sides for example. The objective of our pneumatic bladder is to increase the width of the anterior and posterior dimension while keeping the medial and lateral width narrow. FOR EXAMPLE. The pneumatic bladder when used in our windlass system would increase the plantar to dorsal width while not increasing the medial and lateral dimension.

Cams

Another (PE) embodiment for our ~~artificial muscle~~ viscoelastic devices system uses a cam device wherein the user of our prosthetic system can manipulate the cam by adjusting the cam to increase tension preload our ~~artificial muscle~~ viscoelastic device. These cam devices as shown in figures 14 A ~~and~~ & C can use a worm gear and/or a single or multiple screws to cause the cam to lower and/or raise to tension preload our ~~muscles~~ viscoelastic devices. These cam devices can be attached to the proximal and/or distal end of our monolithically formed ~~calf~~ shank, however, as previously discussed they can be utilized on any prosthetic part that uses our ~~artificial muscle~~ viscoelastic device. The operation of our cam devices is straight forward. For example, our worm gear drive cam device allows the user to screw the worm gear in or out which transfers this rotating motion and power from the worm gear to the gear which is attached to the cam. Other gear types can be used in our cam such as helical, herringbone, bevel, and/or rack and pinion gears.

Figure 14A shows a cam device that does not use a gear operation but rather a simple single and/or multiple adjustment screw. This adjustment screw engages the lower end of the cam and by screwing the screw in and out the motion of the cam is affected. In operation this style of cam device uses the pressure of the artificial muscle to keep the cam engaged with the adjustment screw and/or screws.

Our cams can be made in several different embodiments figure 14C, shows two rotating spindles wherein one or multiple ~~muscles~~ viscoelastic devices can be thread through and/or over the spindles. Figure 14B shows a different style of cam wherein the spindles can be free

to rotate and/or be fixed. Still figure 14 A shows a solid cam wherein spindles are not used. This solid cam design can be made with sides that are longer than the middle to facilitate our ~~artificial muscle~~ VISCO ELASTIC DEVICE tracking. Our cams can be made using any combination of the aforementioned embodiment without straying from our teachings. These cam devices can be made of plastic, alloy, composites and/or any other suitable material. The cam units can be made so they are not solid, they can be made with cutouts and hollows to decrease weight. FIGURE 23 SHOWS A CAM DEVICE MOUNTED ON A SHANK.

-Alternate Embodiment

Cylinder – SOLENOID

Another embodiment for our cam device is a pneumatic, hydraulic, and/or electric cylinder (solenoid) system wherein two cylinders are employed. FIGURE 24 One cylinder (solenoid) is located in our rigid ankle device and the other is located in our cam device see figure ____. This cylinder (solenoid) system is activated by the motion created in the calf shank during physical activity of the user. As the user force loads our prosthetic system anterior longitudinal foot keel the distal end of our calf shank engages the lower cylinder (solenoid) push rod which causes the upper cylinder (solenoid) push rod to engage the cam of the cam device (see figure ~~270~~ #24) in operation as anterior force loading increases the pressure on the lower cylinder increases proportionally which engages the upper cylinder proportionally which causes the cam to engage the muscle creating a proportional tension preload on the artificial muscle. As the force loading increases and/or decreases the tension on the ~~muscle~~ VISCO ELASTIC DEVICE is similarly affected. This creates an

opportunity to allow anterior foot keel variable force loads to dictate variable tension on the artificial muscle. As such this cylinder device creates variable motion outcomes of our calf shank system proportional to the users activites.

FIGURE 25 SHOWS A FEMALE MUSCLE ATTACHMENT DEVICE ATTACHED TO A LEATHER + OR PLASTIC THIGH CUFF, KNEE HINGES ARE ATTACHED TO BOTH THE THIGH CUFF

ALLOY OR PLASTIC

AND A BELOW KNEE SOCKET. THIS FEMALE ATTACHMENT PLATE COULD ALSO BE LOCATED ON THE BACK OF THE CALF AREA OF A PROSTHETIC SOCKET.

FIGURE 26 SHOWS AN ALTERNATIVE WINDLASS DEVICE WHICH IS SIMILAR TO FIG 27 THIS WINDLASS CABLE CAN INCORPORATE A VISCOELASTIC + OR LEAFSPRING DEVICE TO ADD ~~BE~~ INCREASED ELASTIC ENERGY STORAGE CAPACITY. THE ~~WINDLASS~~ WINDLASS CABLE CAN BE A ~~STRAP~~ NON STRETCHABLE + OR ~~STRETCHABLE~~ ELASTIC STRAP + OR CABLE. THIS EMBODIMENT ATTACHES THE PROXIMAL CALF TO THE ~~DISTAL~~ ~~AREA~~ ~~TO~~ FOREFOOT REGION OR THE FOOT KEEL. THIS WINDLASS DEVICE CAN INCORPORATE ALL PREVIOUS DISCUSSED VISCOELASTIC ~~&~~ LEAF SPRING DEVICES CAMS BLADDERS + PADS AS ONE

skilled in the art would know to
increase the PE + RE of this
device to improve kinetic power
generation. FIG 28 shows ~~a~~
~~this cable~~ single cable system that
runs through the posterior aspect
of the root keel this area
can include two roller wheels
similar in design to the roller wheel
THAT IS proximal to this area. Another embodiment
would be to run the cable through
two holes in the root keel which
are located more anteriorly.

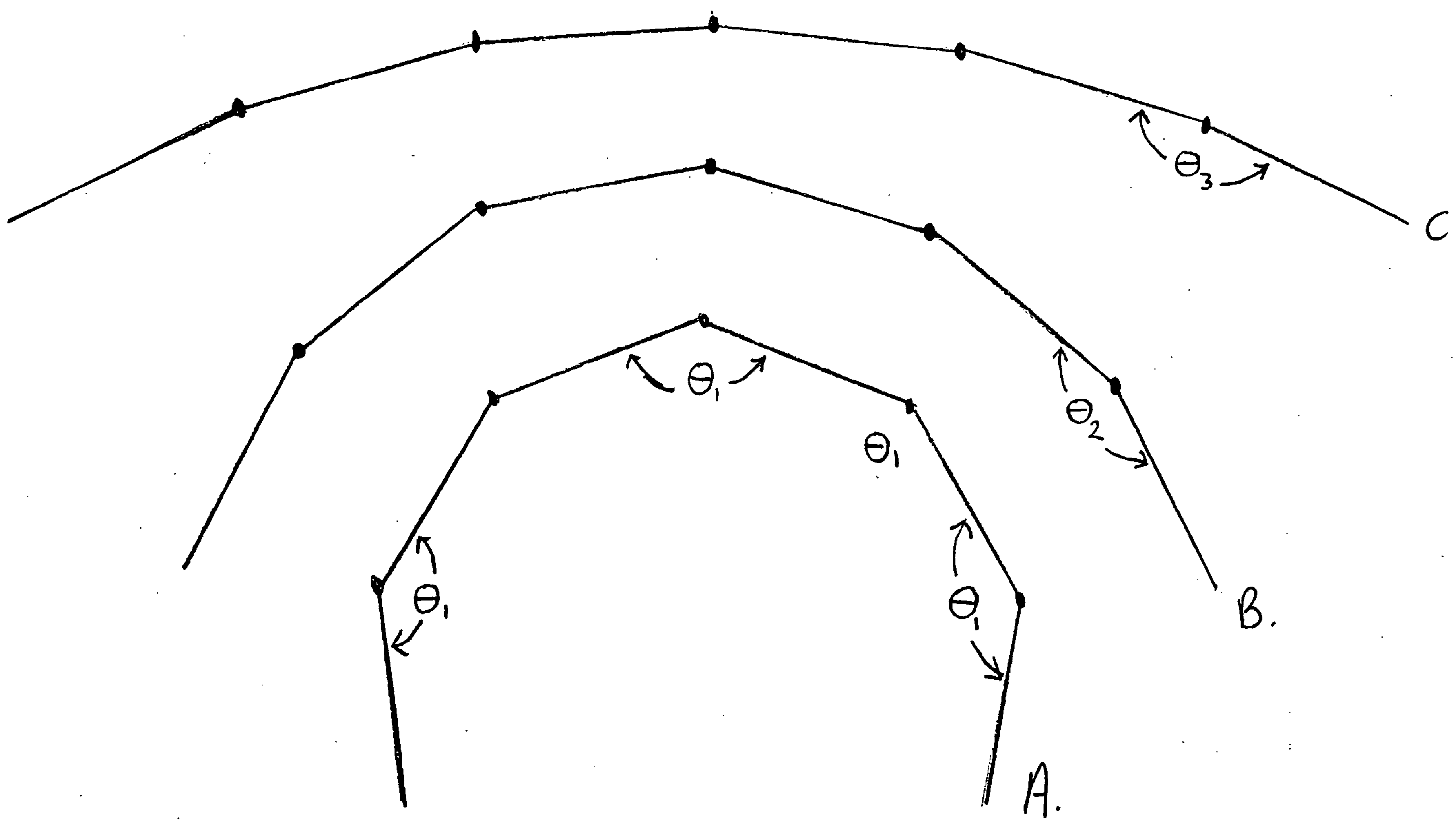
SAMPLE 29 SHOWS ANOTHER ALTERNATIVE EMBODIMENT TO OUR ARTIFICIAL MUSCLE DEVICE ~~FOR~~ SINGLE OR MULTI SPRING OF VARYING ELASTICITY COULD BE EMPLOYEED IN THIS DESIGN. THE SPRINGS CAN BE MADE OF ALLOY, PLASTIC COMPOSITES, OR ANY OTHER SUITIBALE MATERIAL WITH OUT VARYING FROM THE TEACHINGS ~~OF~~ OF THIS PATENT.

ATTACHMENT (A)

C. $\theta_3 = 170^\circ$

B. $\theta_2 = 155^\circ$

A. $\theta_1 = 140^\circ$



TO FURTHER SUPPORT OUR CONTENTION
THAT THE ANGULAR VELOCITY OF A
CURVILINEAR MECHANICAL STRUCTURE
CAN BE AFFECTED POSITIVELY (INCREASED) + OR
NEGATIVELY (DECREASED) BY THE DIRECTION
OF MOVEMENT WHEREIN MOVEMENT
OF THE ~~SD~~ CURVILINEAR STRUCTURE ~~CHANGES~~ CAUSES
THE RADI OF THE MECHANICAL STRUCTURE TO INCREASE + OR DECREASE
IN SIZE IN RESPONCE TO A FORCE. FIG ___
A B + C REPRESENT THREE CURVILINEAR
STRUCTURES THAT HAVE BEEN CREATED
BY ARTICULATING 6 SEPERATE LINK
SEGMENTS (·), ~~WHICH~~ THESE SEPERATE LINK 500
SEGMENTS ARTICULATE AT (·)+θ CREATING

5 SEPERATE BUT EQUAL Θ ANGLES PER STRUCTURE.

STRUCTURE A HAS θ_1 ANGLE OF 140°

~~Ø~~ STRUCTURE B + C HAVE ~~THE~~ θ_2 ; θ_3 ANGLES OF 155° + 170° RESPECTIVELY.

THE THREE STRUCTURES REPRESENT THREE DIFFERENT RADI CURVILINEAR STRUCTURES. STRUCTURE A HAVING A SMALLER RADIUS THAN B AND B SMALLER THAN ~~C~~ C.

ANGULAR VELOCITY IS DEFINED ~~AS~~ AS ANGULAR CHANGE OVER TIME. IF STRUCTURE A θ_1 WAS CHANGED OVER TIME TO θ_2 ~~AND~~ THE CHANGE IN $\theta_2 - \theta_1$ REPRESENTS ~~A~~ A 15° INCREASE IN ANGULAR CHANGE

501

FOR EVERY Θ ANGLE. THIS SHOWS THAT

A MECHANICAL STRUCTURES ANGULAR VELOCITY CAN BE AFFECTED (INCREASED) OVER TIME AND ITS ANGULAR VELOCITY POTENTIAL IS DIRECTLY ~~R~~ RELATED TO THE SIZE OF THE RADI CURVILINEAR STRUCTURE. SIMILARILY IF STRUCTURE C WAS CHANGED (OVER THE SAME AFORMENTIONED ~~THIS SAME~~ TIME FRAME) TO STRUCTURE A IT WOULD REPRESENT A DECREASE ~~CHANGE~~ IN Θ (Θ_3 170° MINUS Θ_1 140°) OF 30°. IN THIS SCENERION ~~SINCE~~ THE Θ ANGLE IS GETTING SMALLER WHICH CAUSES A DECREASE IN ANGULAR VELOCITY POTENTIAL ~~IS~~

~~CREATED. OUR EACH CHANGE TO~~

506

AS PREVIOUSLY DISCUSSED OUR PROTOTYPES ~~P2~~ P1 + P2 SHANK + LONGITUDINAL ARCH OF THE FOOT KEEL ~~TRESPOUND~~ RESPOND TO LATE MIDSTANCE PHASE OF GAIT GROUND REACTION FORCE BY EXPANDING ~~@~~ THIS WOULD REPRESENT A ~~A~~ ~~INCREASE~~ MOVEMENT OF FIGURE _A TOWARDS FIGURE__ ($\theta 170$ minus $\theta 140 = 30°$ ~~@~~ INCREASE IN ANGULAR CHANGE). C ON THE OTHER HAND THE FLEXFOOTS MONOLITHICALLY SHAPED FOOTKEEL ANKLE AND SHANK IN RESPONSE TO THIS SAME (GRF) WOULD MOVE FROM FIGURE_C $\theta 170°$ TO FIG__ A $\theta 140°$ ~~WHE 140 $\theta 170 - \theta 140$~~ A 30° DECREASE IN ANGULAR CHANGE. AS A CONSEQUENCE THE AFOREMENTIONED PROTOTYPES ~~OUR~~ STRUCTURES HAVING AN INCREASE IN ANGULAR VELOCITY POTENTIAL WHERE AS THE ~~F~~ FLEXFOOT PROSTHESIS HAS A

507

Decrease in angular velocity potential.

As mentioned earlier in this proposal ankle joint ~~kinetic~~ sagittal plane kinetic power equals ~~KP~~ moments of ~~[illegible]~~ ankle joint force (which are very similar in magnitude for the Flex Foot and ~~[illegible]~~ prototypes) ~~[illegible]~~ times angular velocity, ~~an increase~~ since ~~[illegible]~~ angular velocity is a product of moments of force ~~[illegible]~~ an increase in angular velocity will directly & postively affect the kinetic power where as a decrease in angular

VELOCITY WILL NEGATIVELY AFFECT

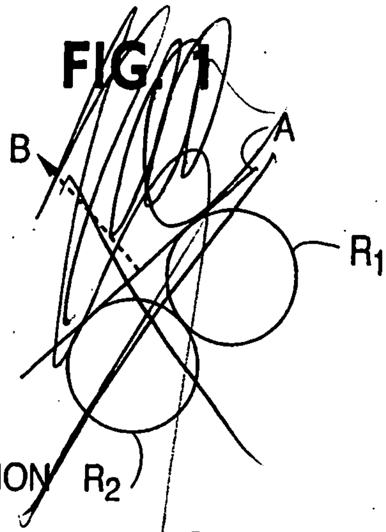
THE KINETIC POWER GENERATION.

THIS IS ABOUT AS GOOD AS IT GETS.

509

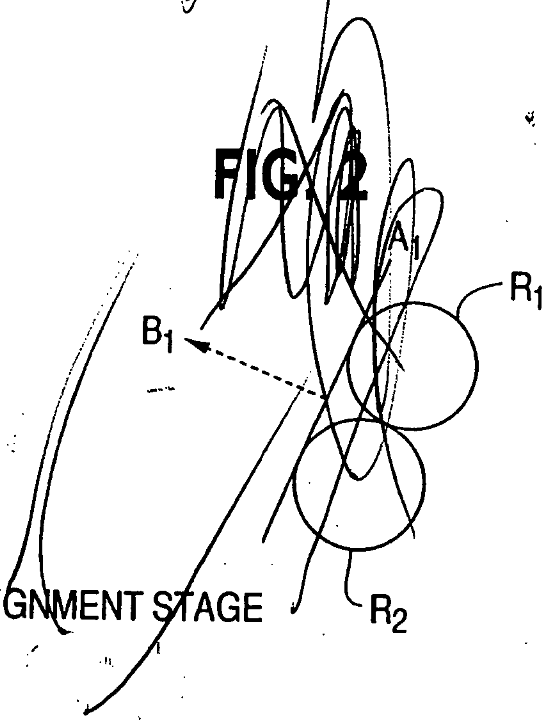
1,000,000 ANOTHER OBJECTIVE OF OUR ~~[illegible]~~ VISCOELASTIC + LEAF SPRING ~~[illegible]~~ ELASTIC ENERGY STORING DEVICES IS TO INCREASE THE ELASTIC ENERGY STORAGE CAPACITY OF THE ENTIRE ~~[illegible]~~ PROSTHETIC SYSTEM. WITH ~~[illegible]~~ EACH SEPARATE COMPONENT FOOT HEEL SHANK ~~POSTERIOR~~ ~~[illegible]~~ VISCOELASTIC + LEAF SPRING DEVICE: HAVING ITS OWN ELASTIC ENERGY STORAGE CAPACITY. WHERE IN THE ~~[illegible]~~ COMPONENTS CAN BE TUNED TO REPLICATE HUMAN ANKLE MOTION FOR VARIED ACTIVITIES.

FIG. 1



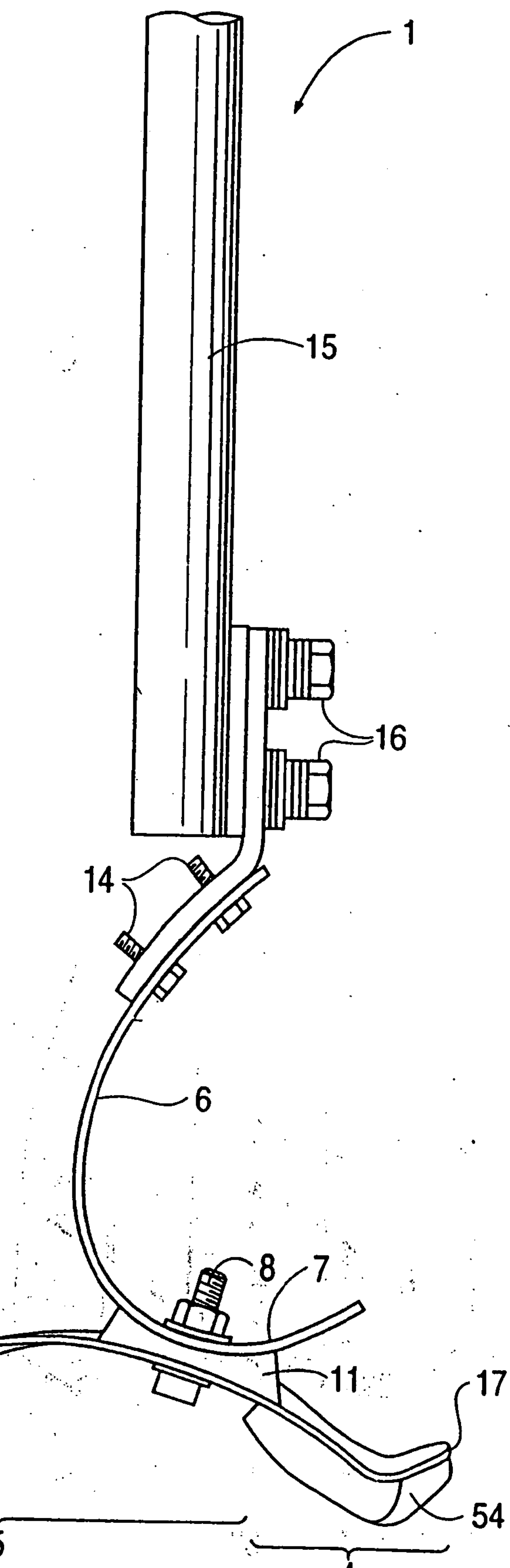
START POSITION

FIG. 2



ALIGNMENT STAGE

FIG. ~~2~~ 1



~~FIG. 25~~ FIG 2

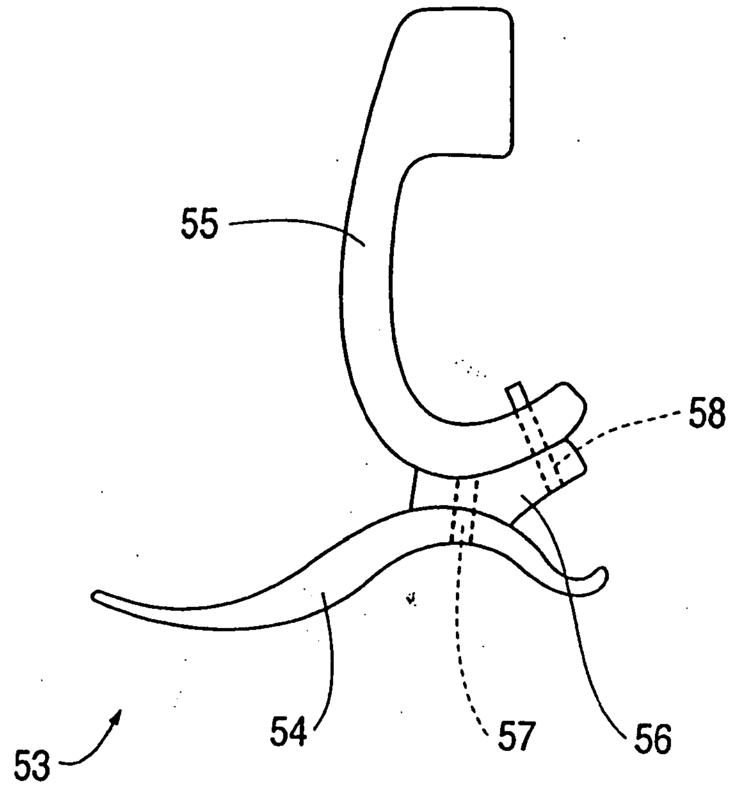
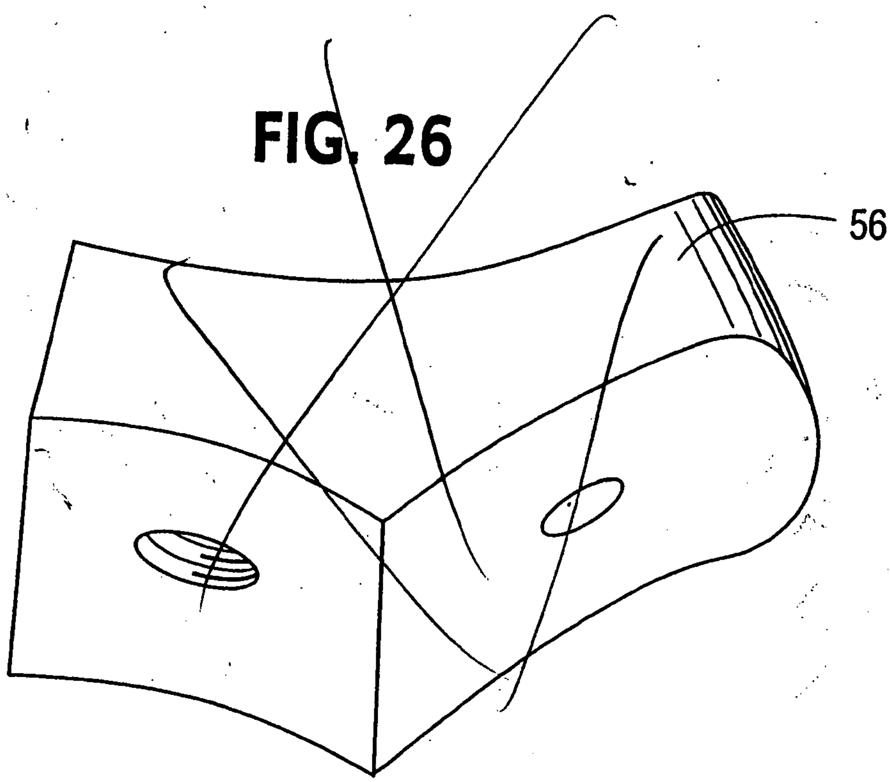
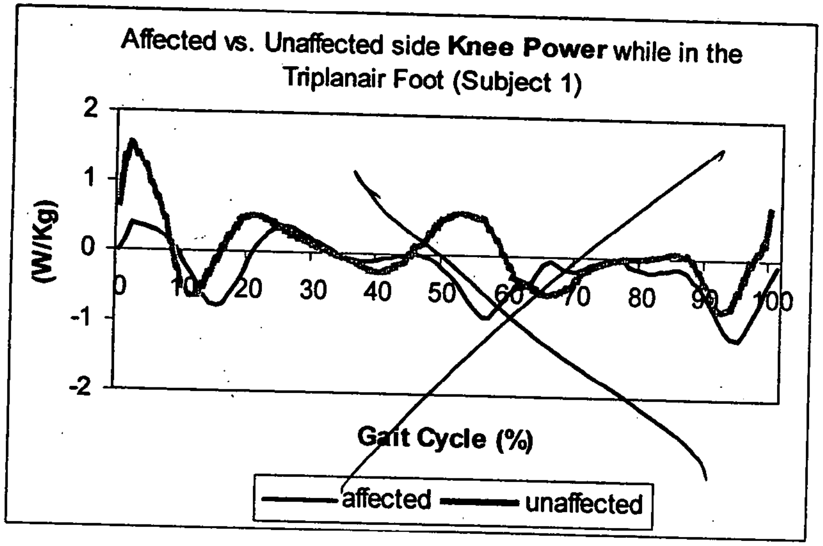


FIG. 26




Affected vs. Unaffected side Knee Power while in the Triplanair Foot (Subject 1)
(W/Kg)
2
1
0
-1
-2
0
10
20
30
40
50
60
70
80
90
100
Gait Cycle (%)
affected
unaffected

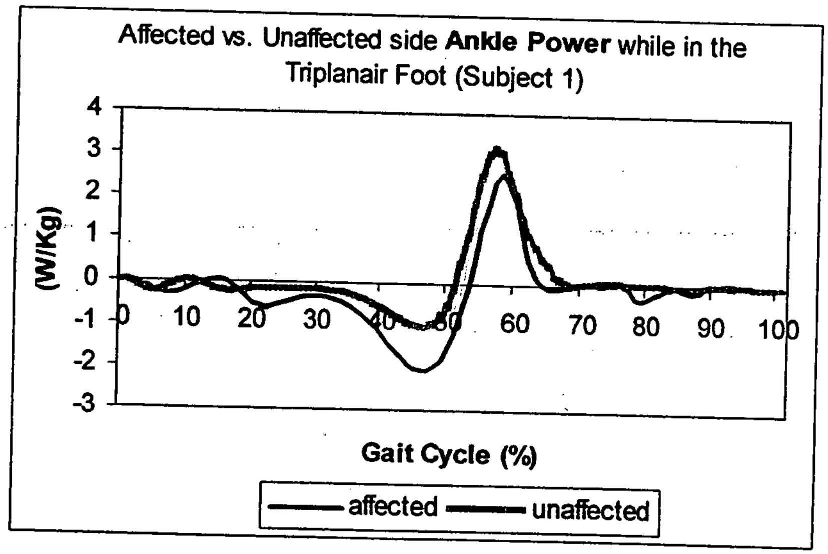
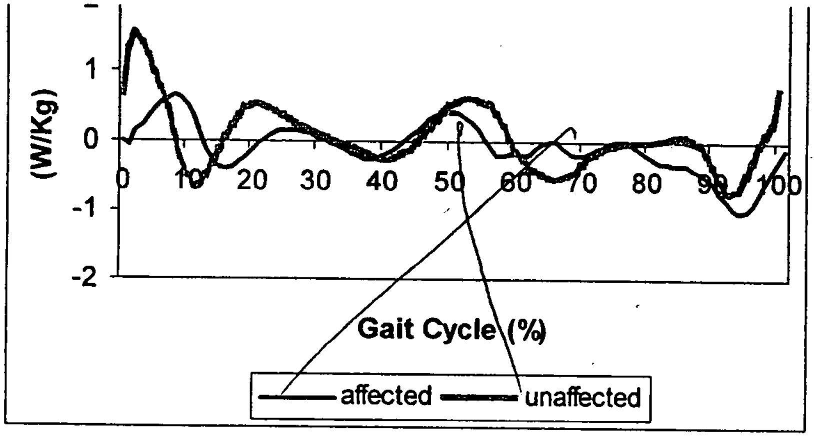
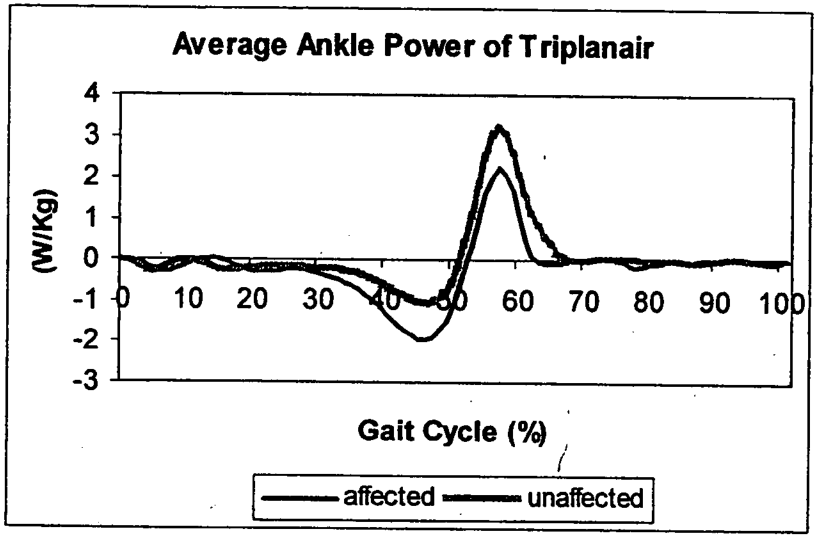

Affected vs. Unaffected side Ankle Power while in the Triplanair Foot (Subject 1)
(W/Kg)
4
3
2
1
0
-1
-2
-3
0
10
20
30
40
50
60
70
80
90
100
Gait Cycle (%)
affected
unaffected

FIG 3

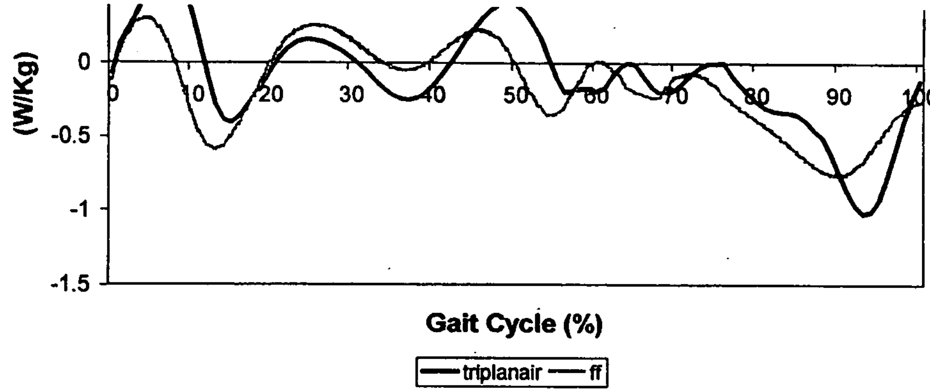




R164

TAB 3

TAB 4



Average **Ankle Power** Generation Curve of the Triplanair vs. the Flex-Foot

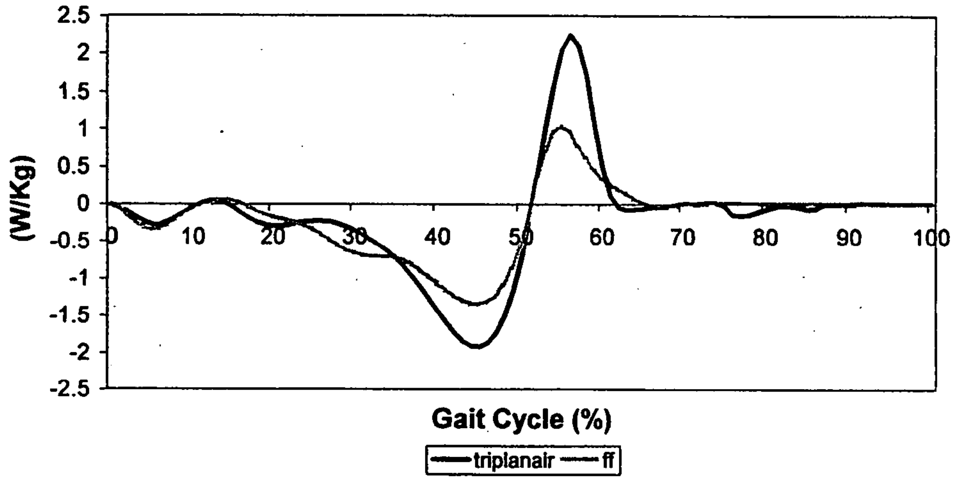


FIG. 5

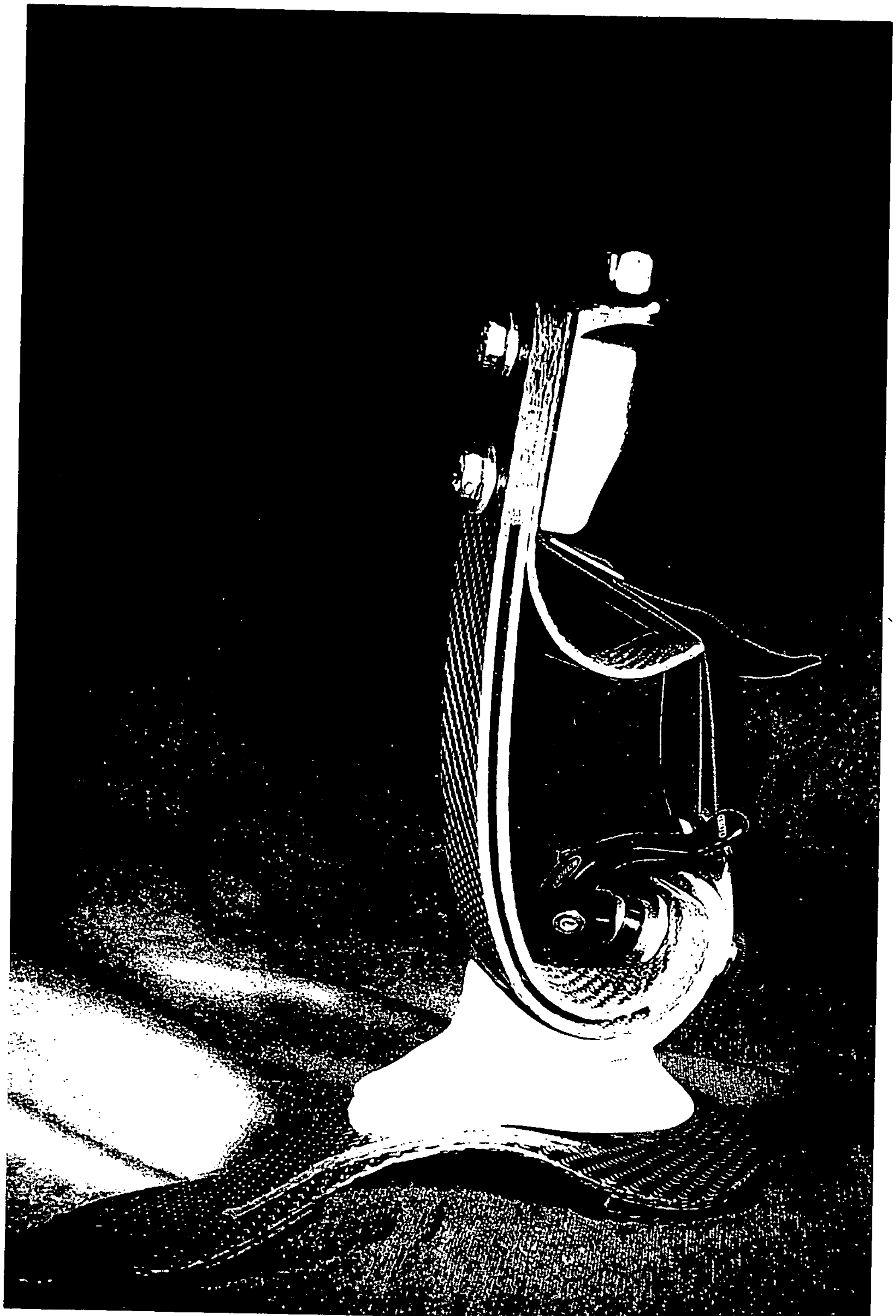


FIGURE 6

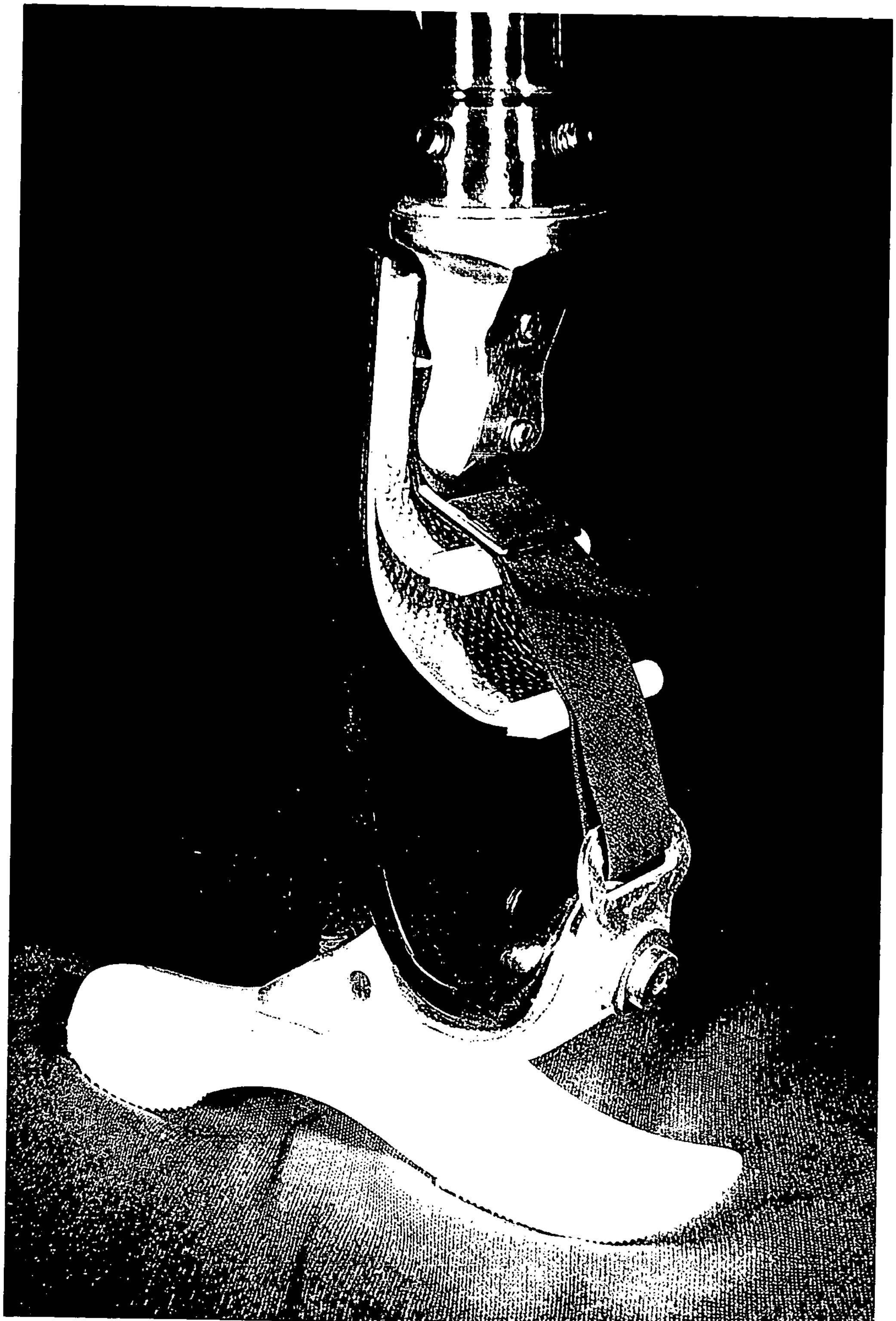


FIGURE 7

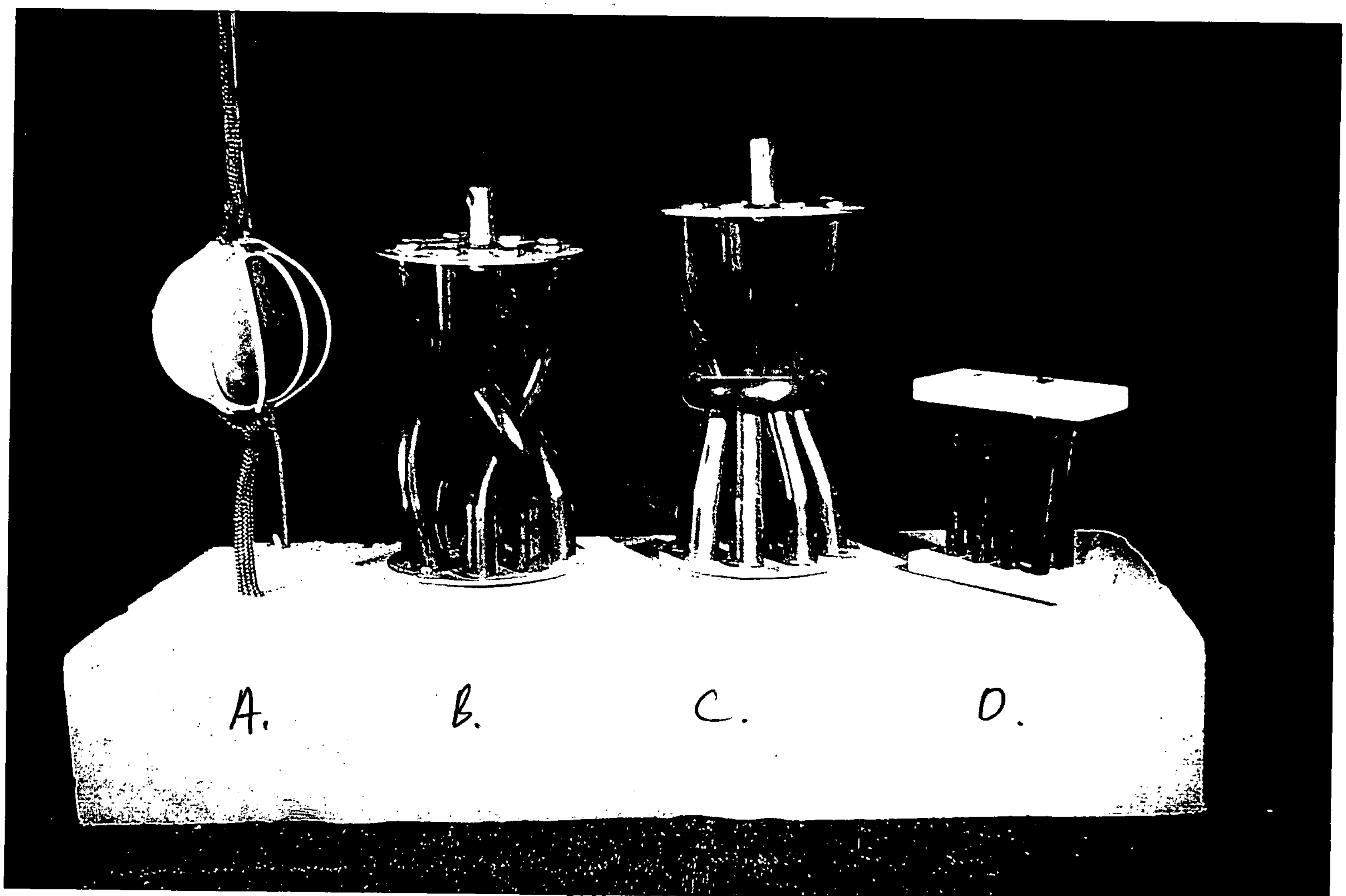
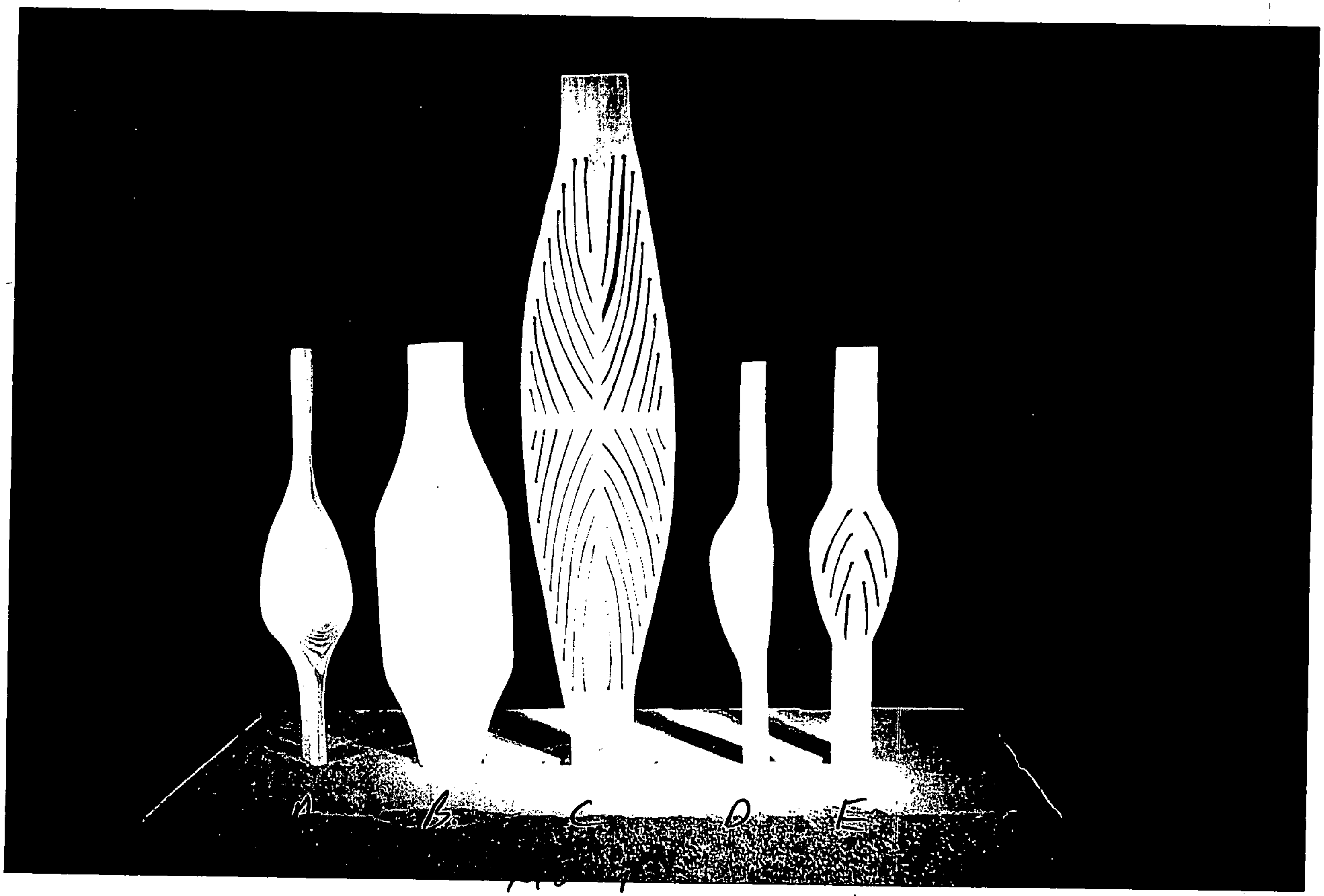


FIG 8


A
B
C
D
E

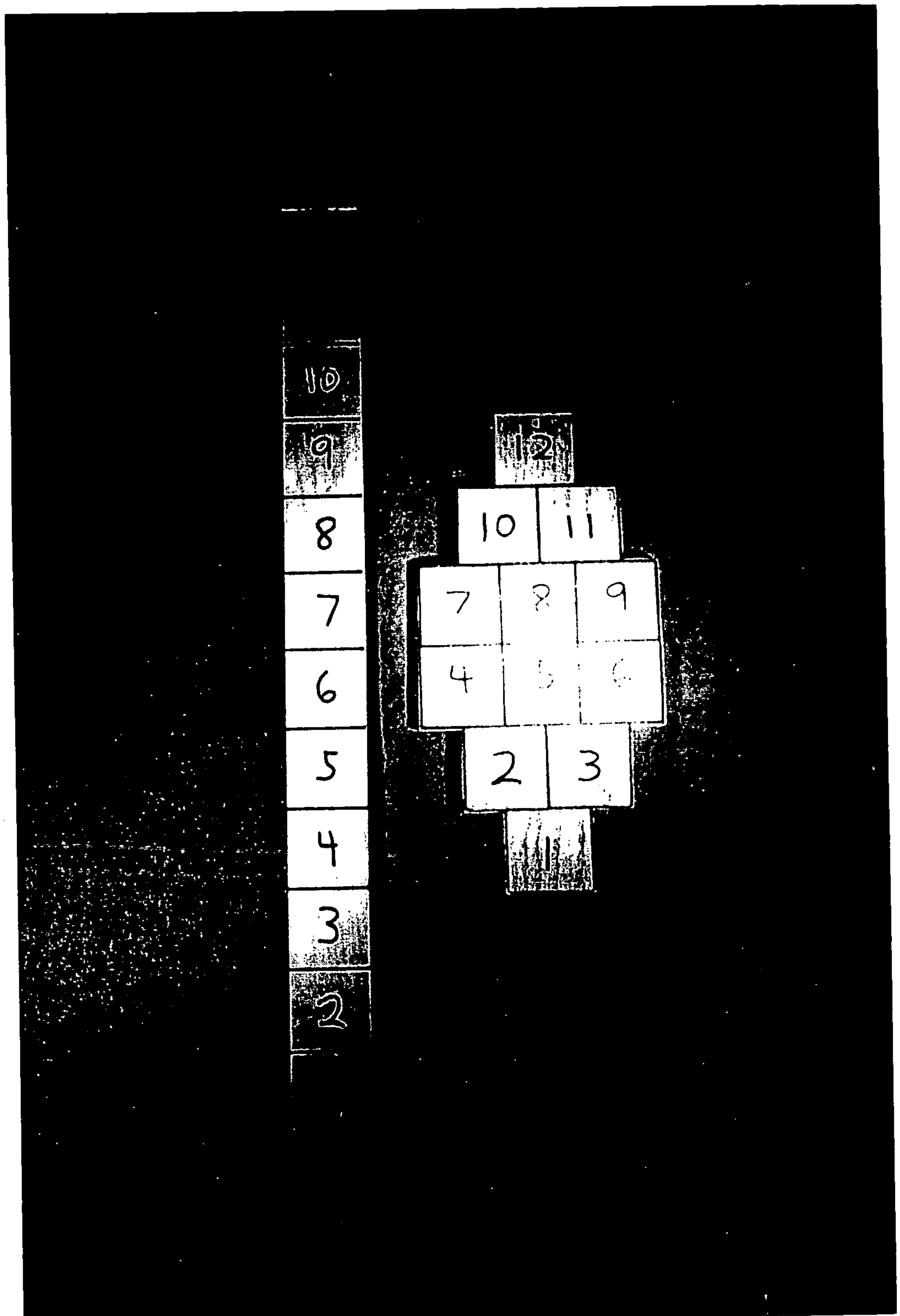


FIGURE 10

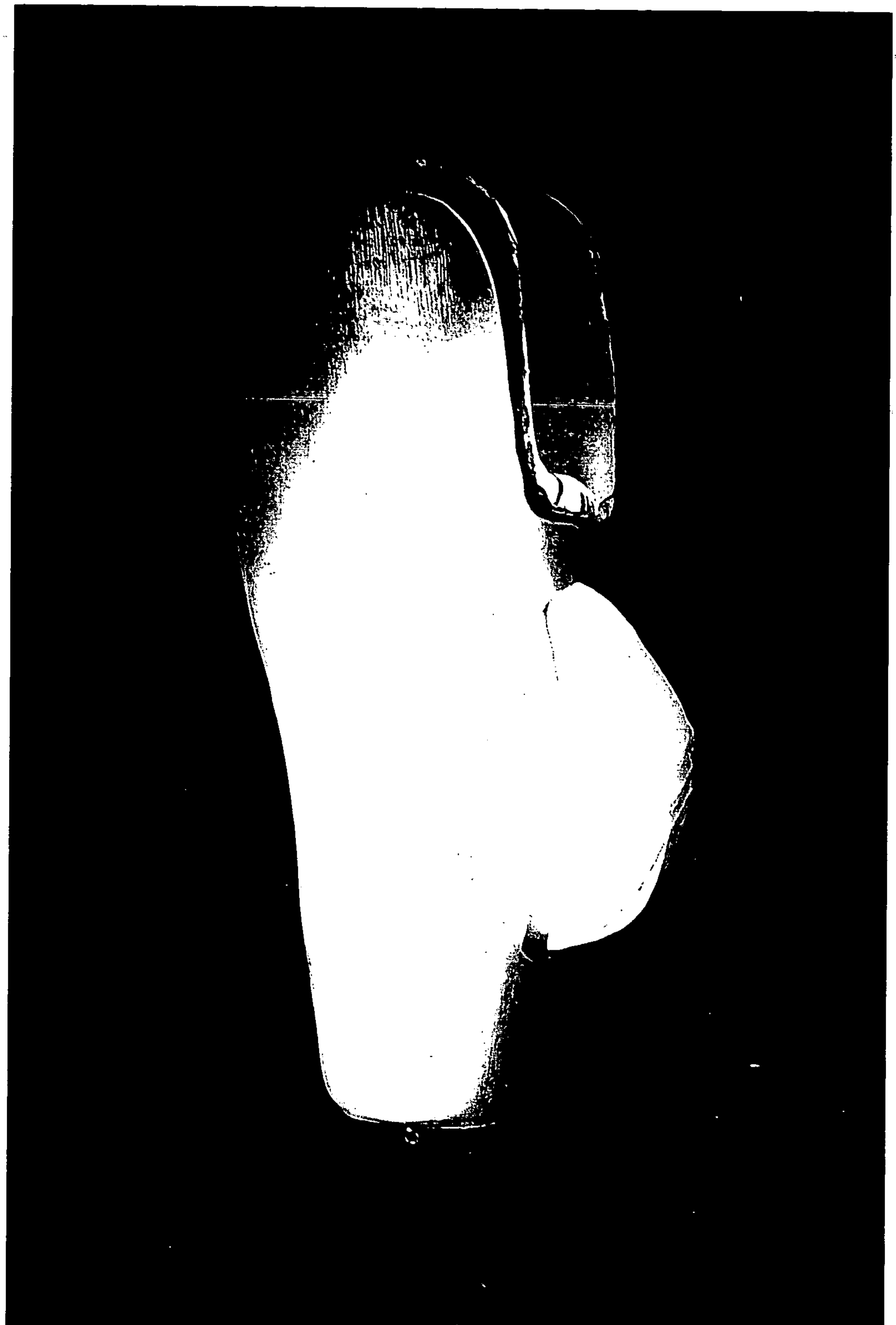


FIGURE 11

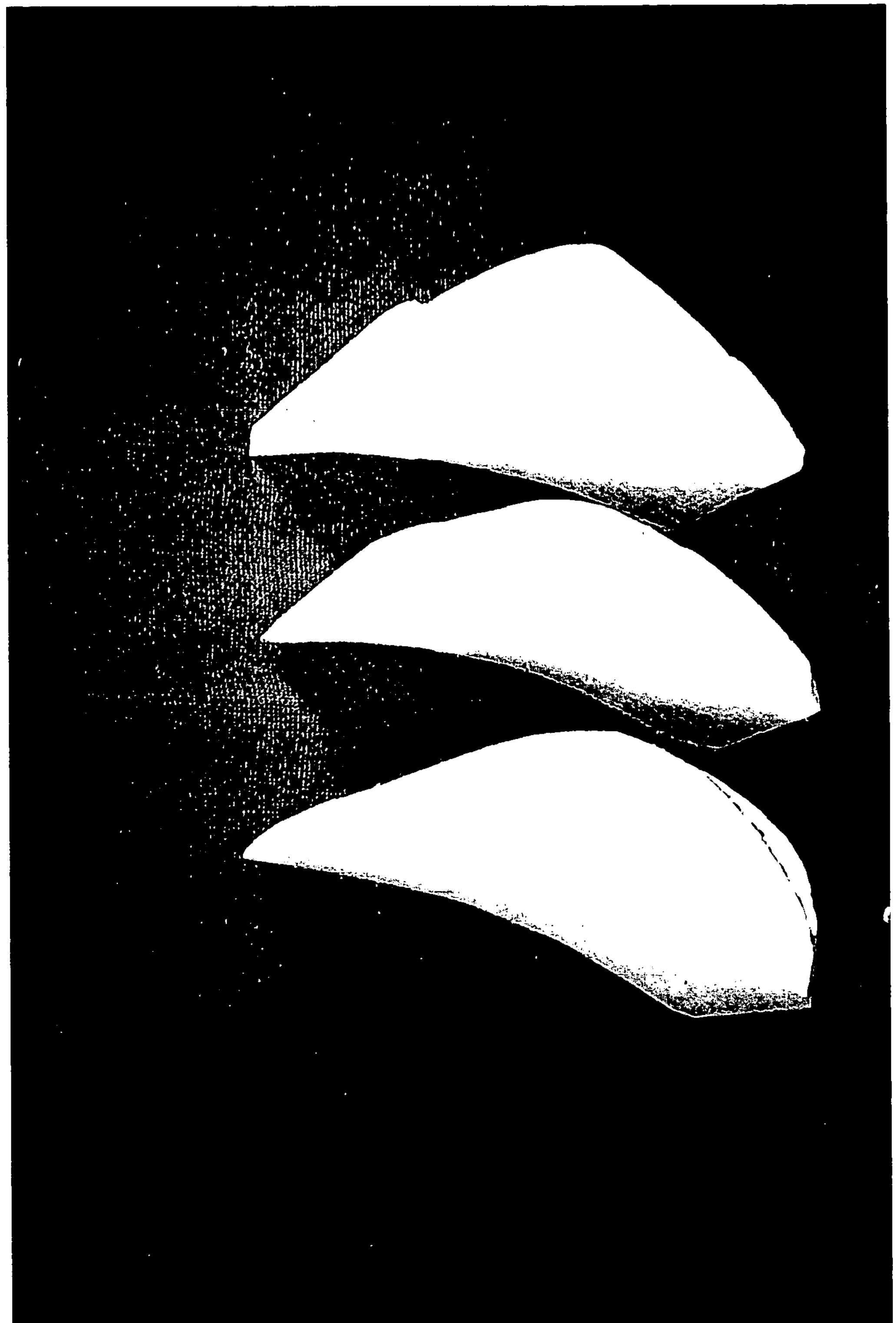


FIG 12

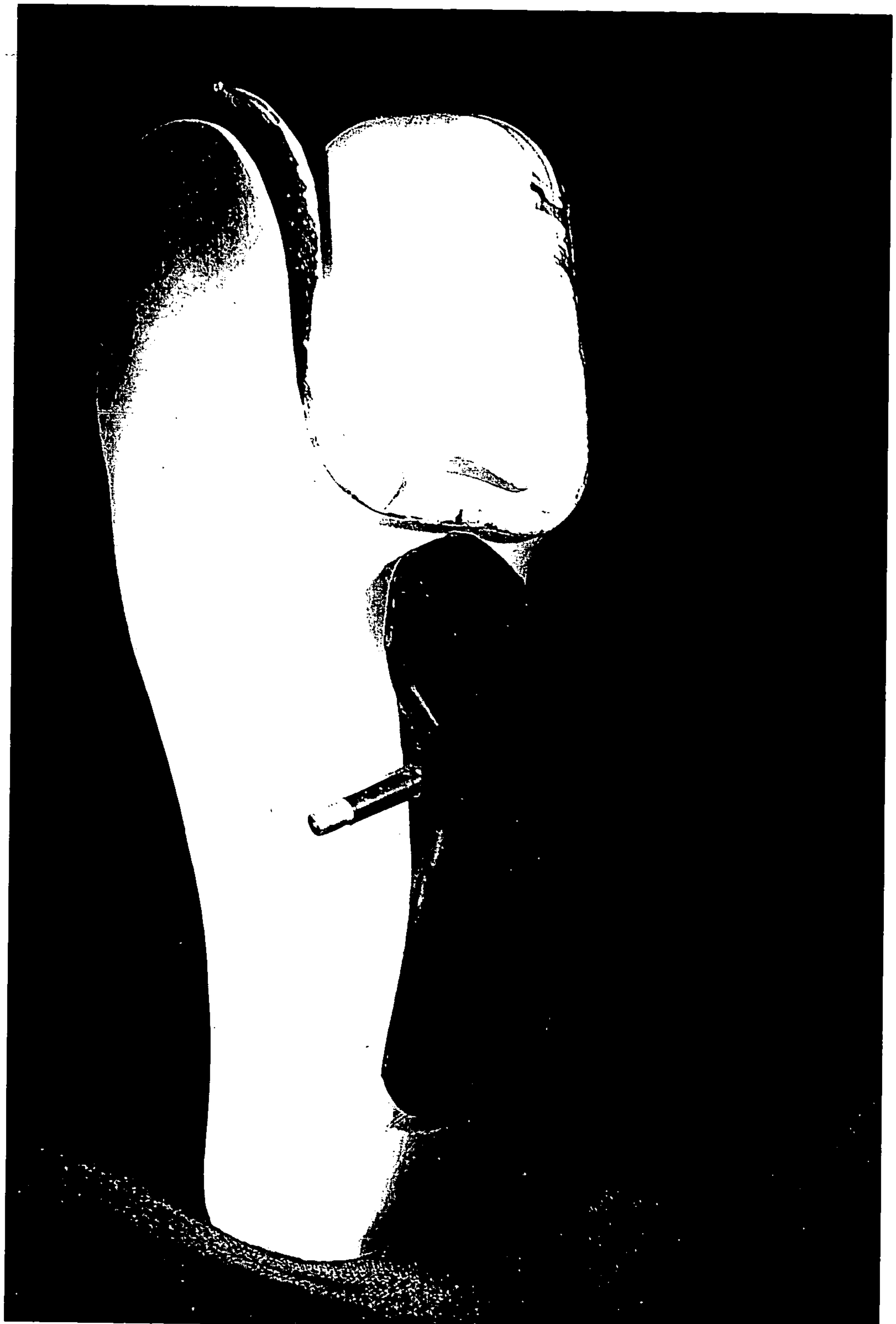
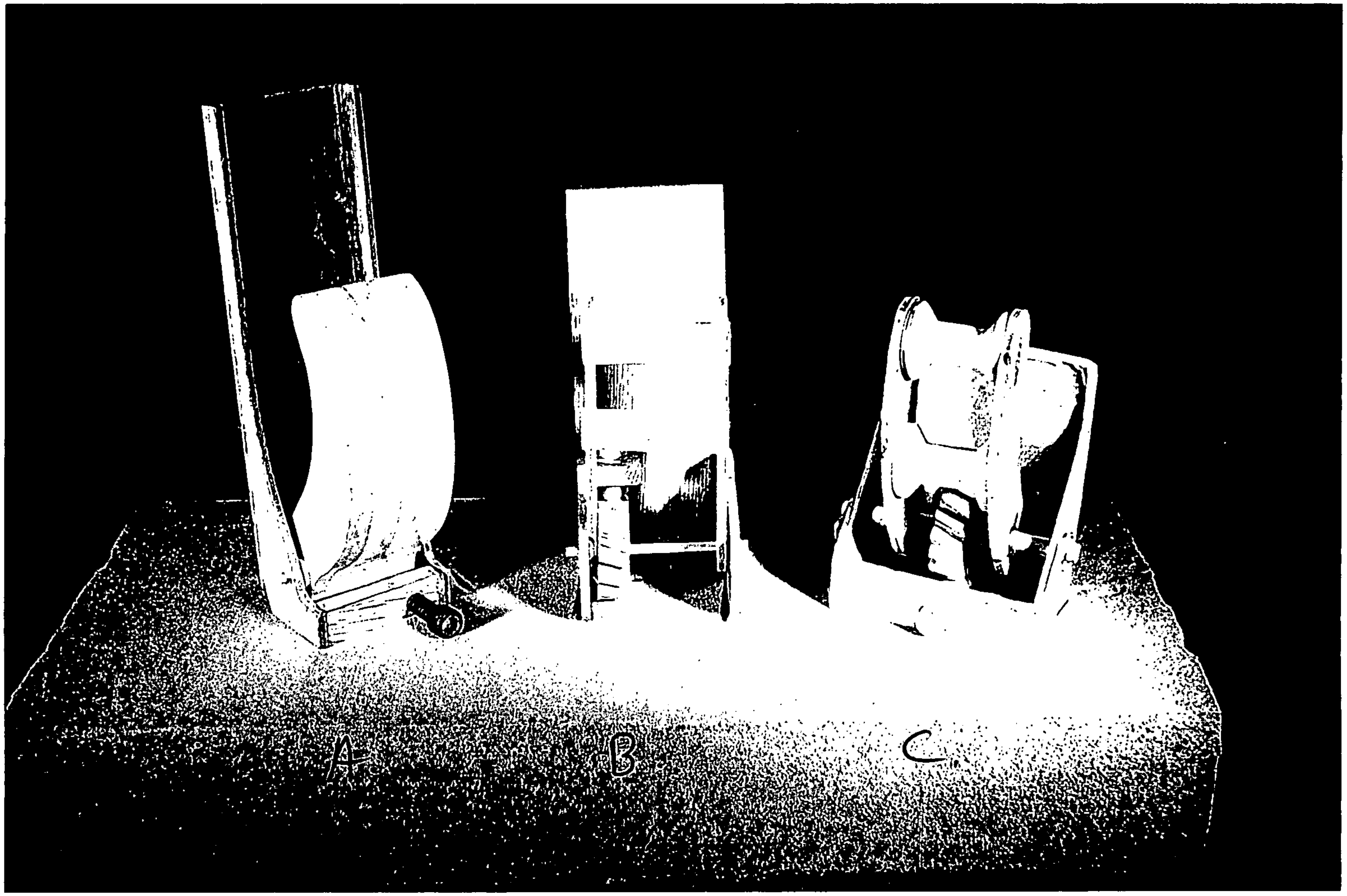


Figure 13


A
B
C

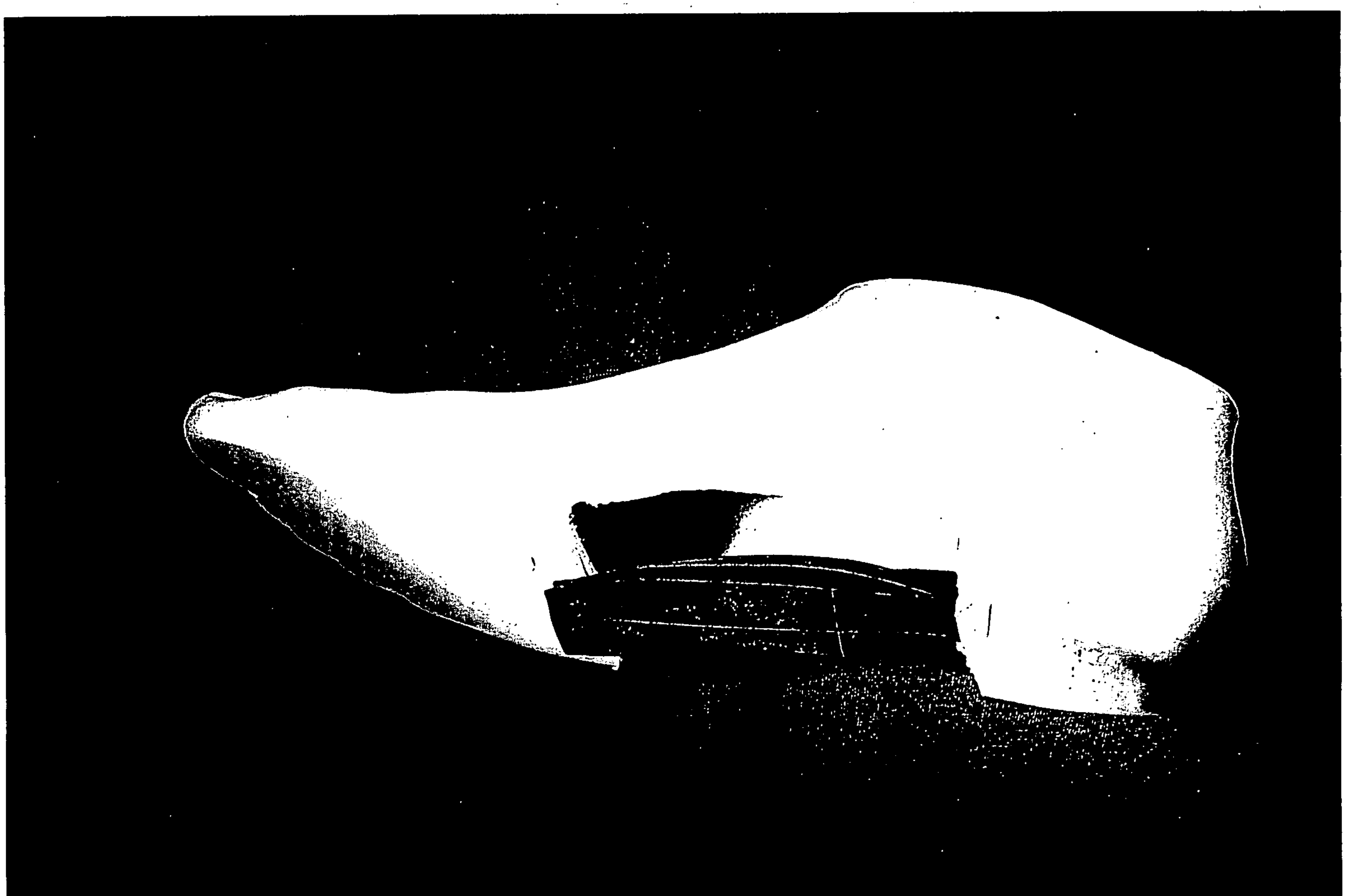


FIG 15

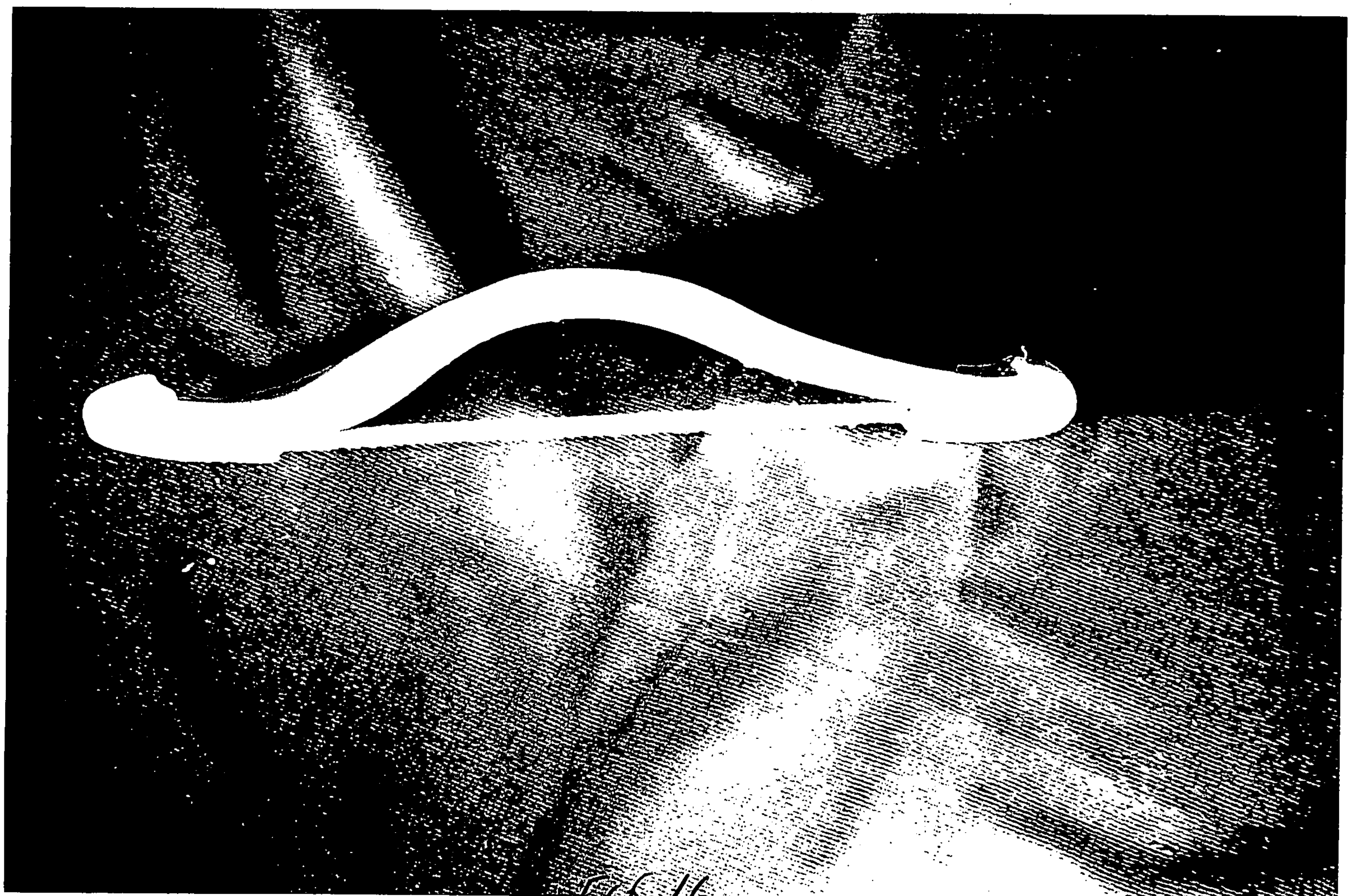
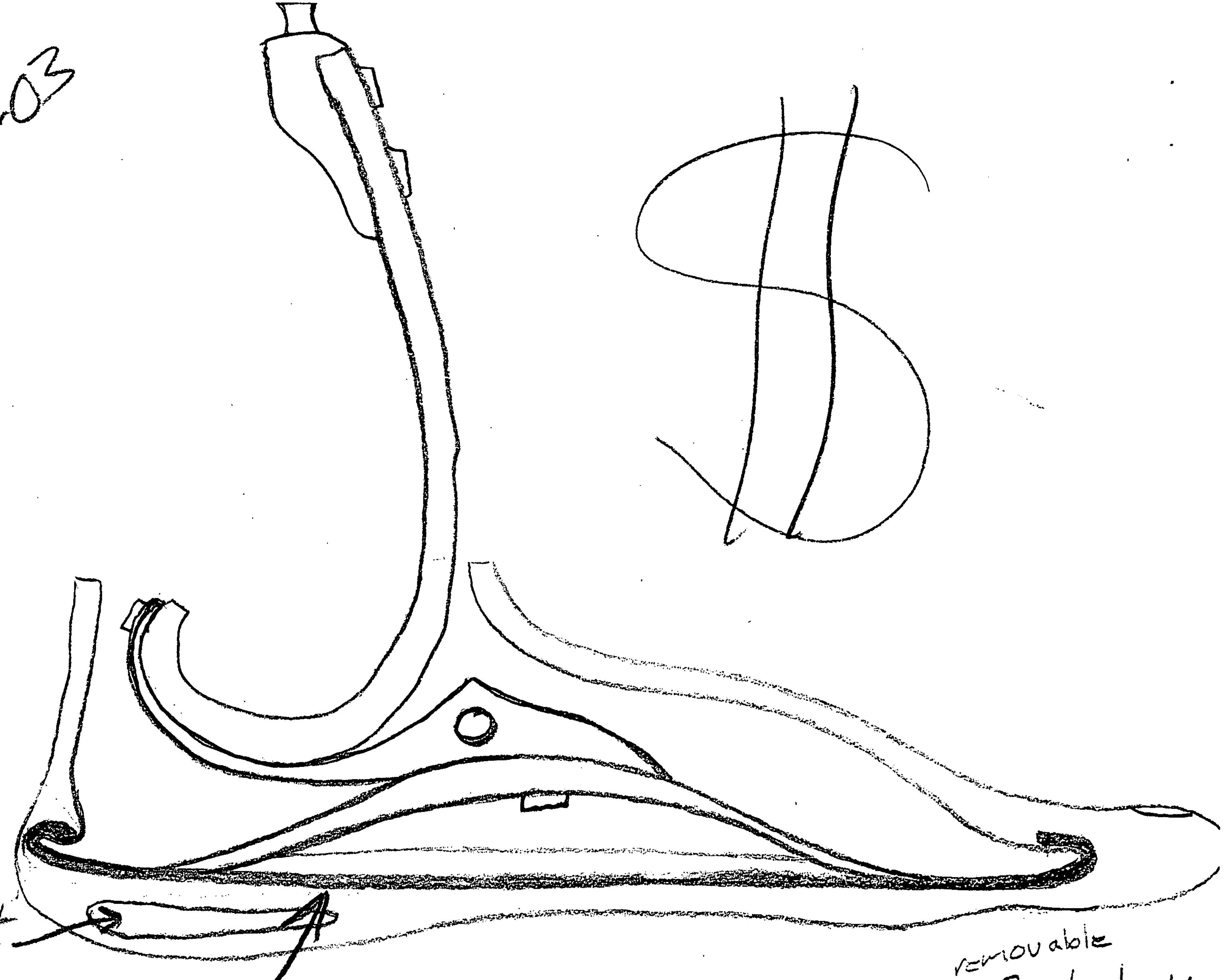


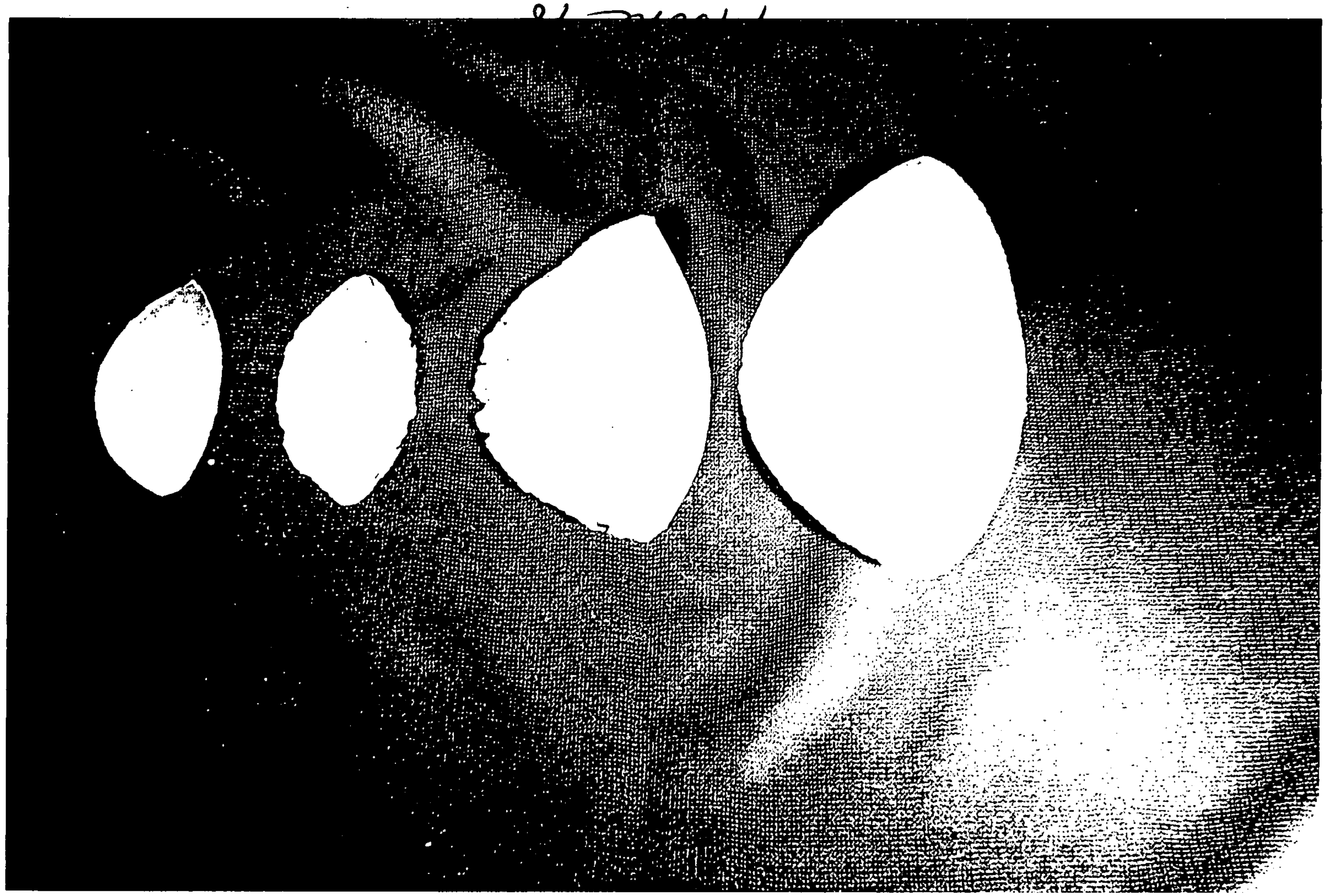
FIG 16

7-20-03



ELASTIC STRAP OR EQUAL EMBEDDED IN removable footshell
To aid IN Dynamic return of footkeel

FIG 17



19

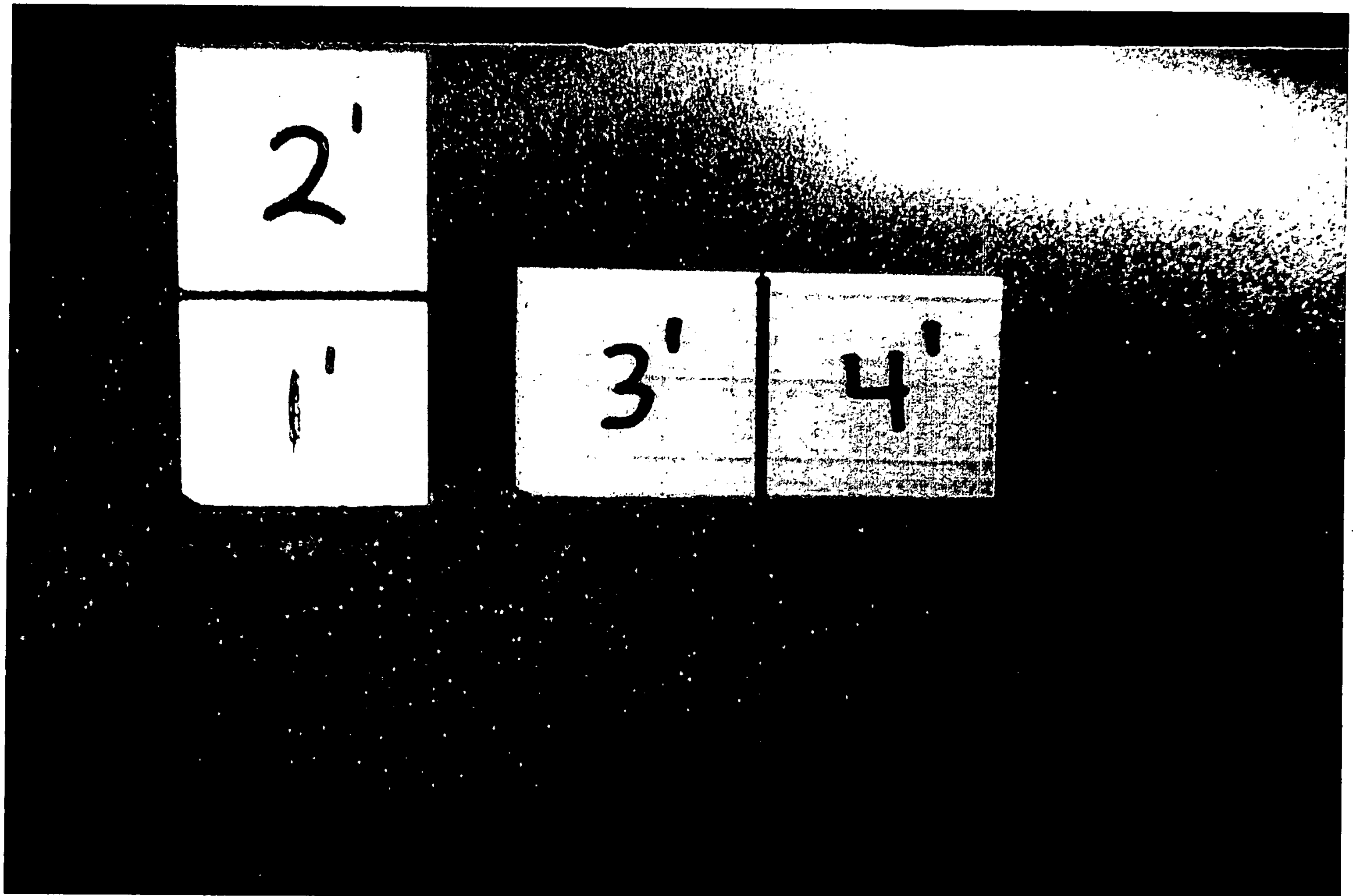
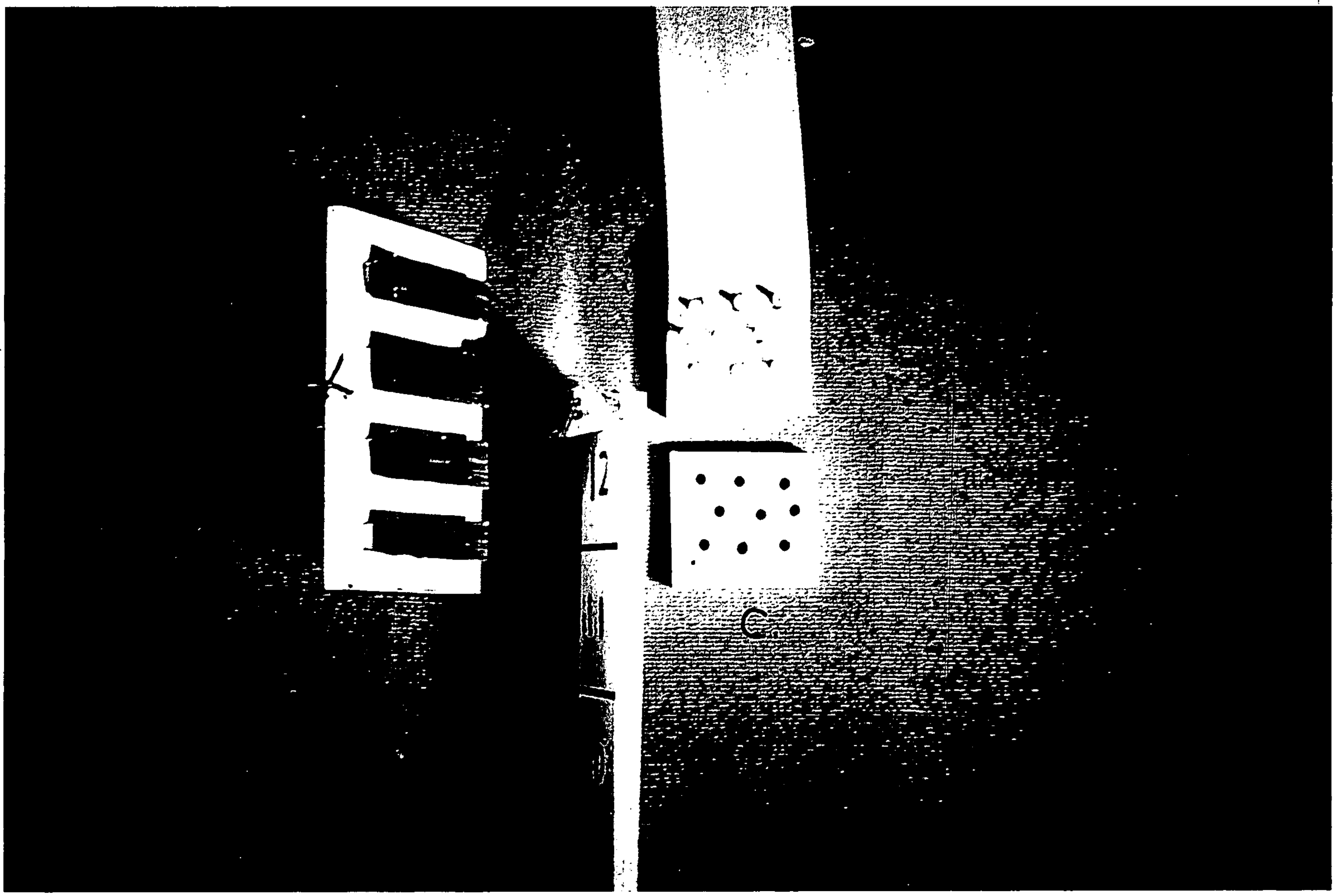


FIG 19

FIG 20



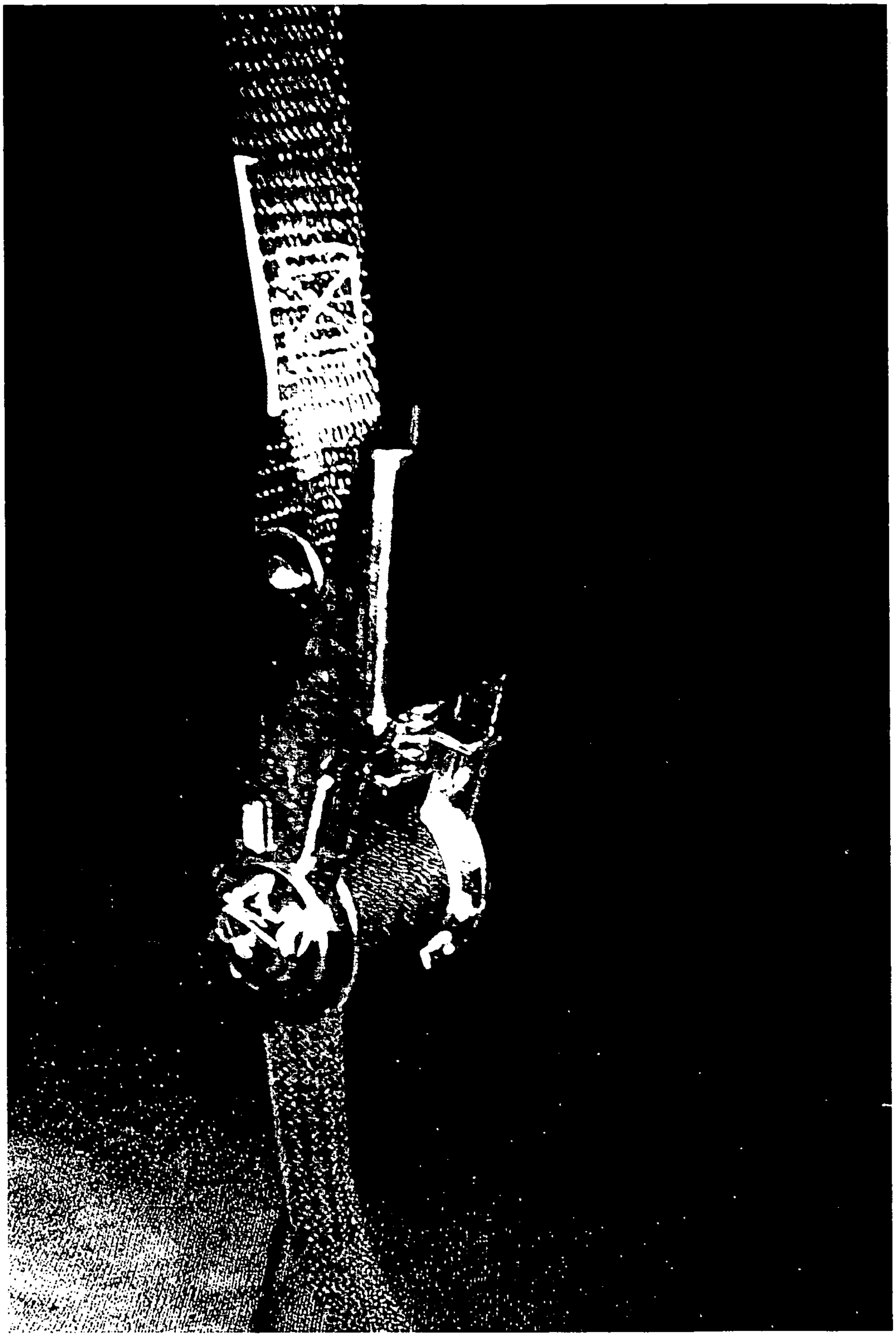


FIGURE 21

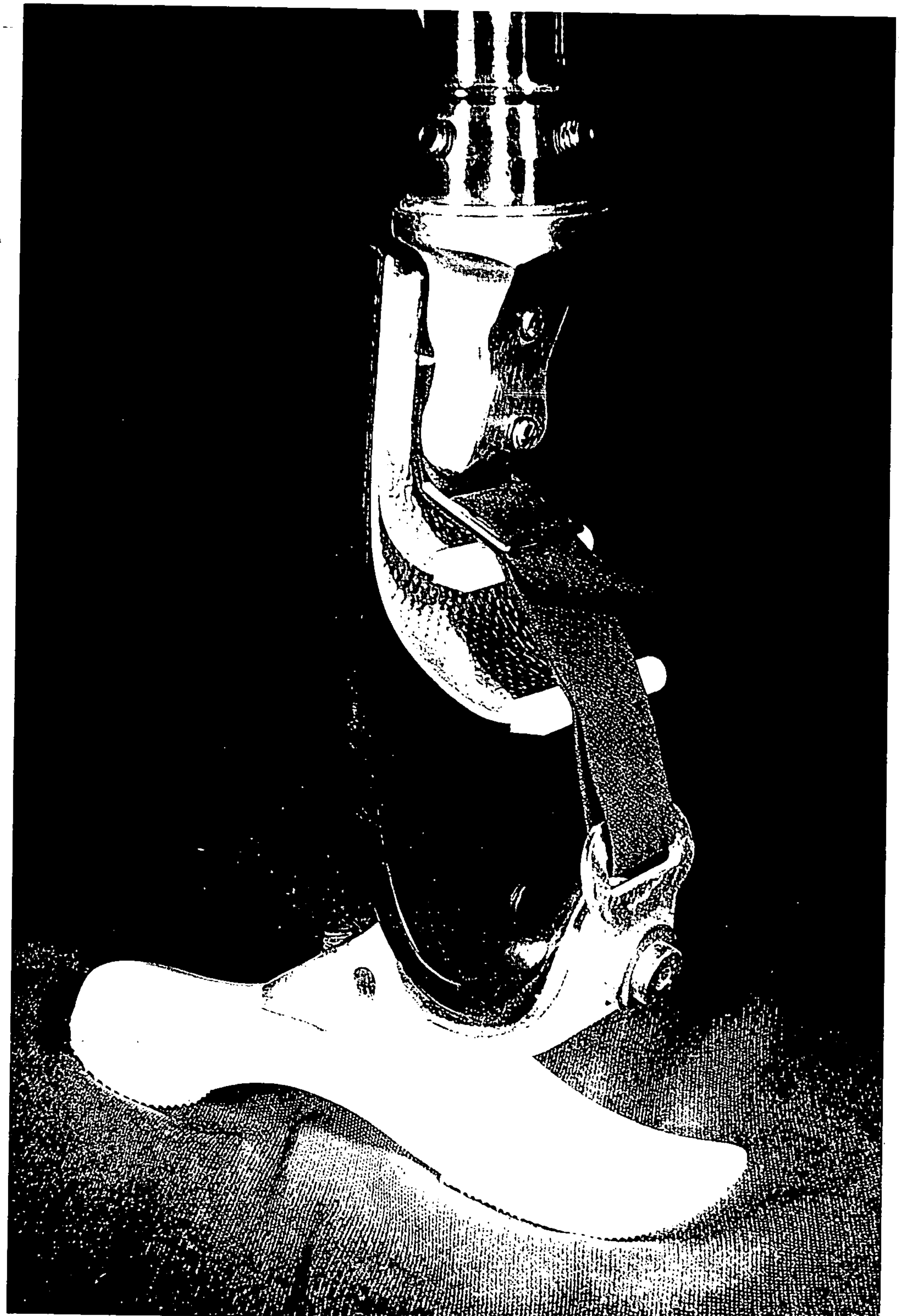
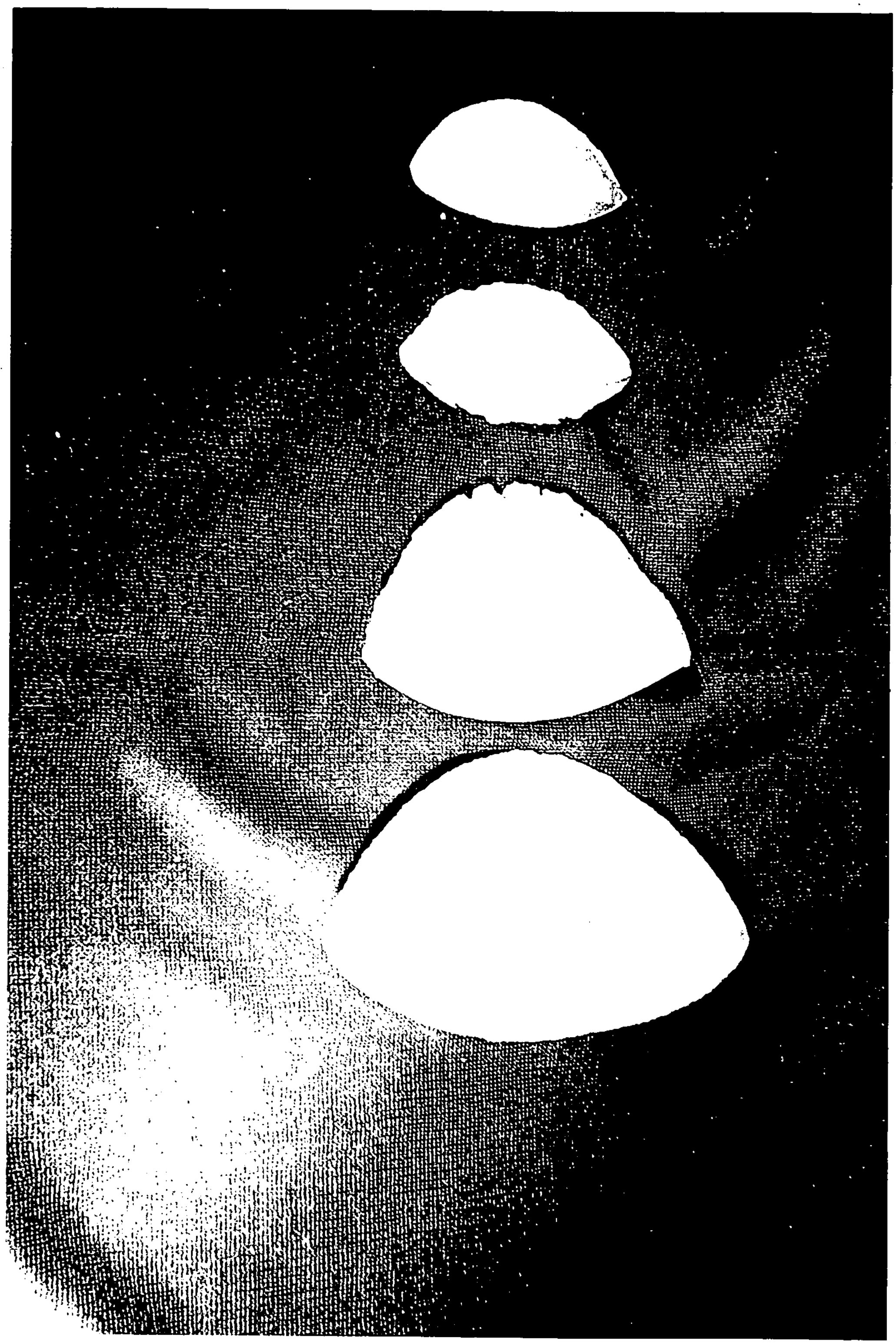


FIG 21A



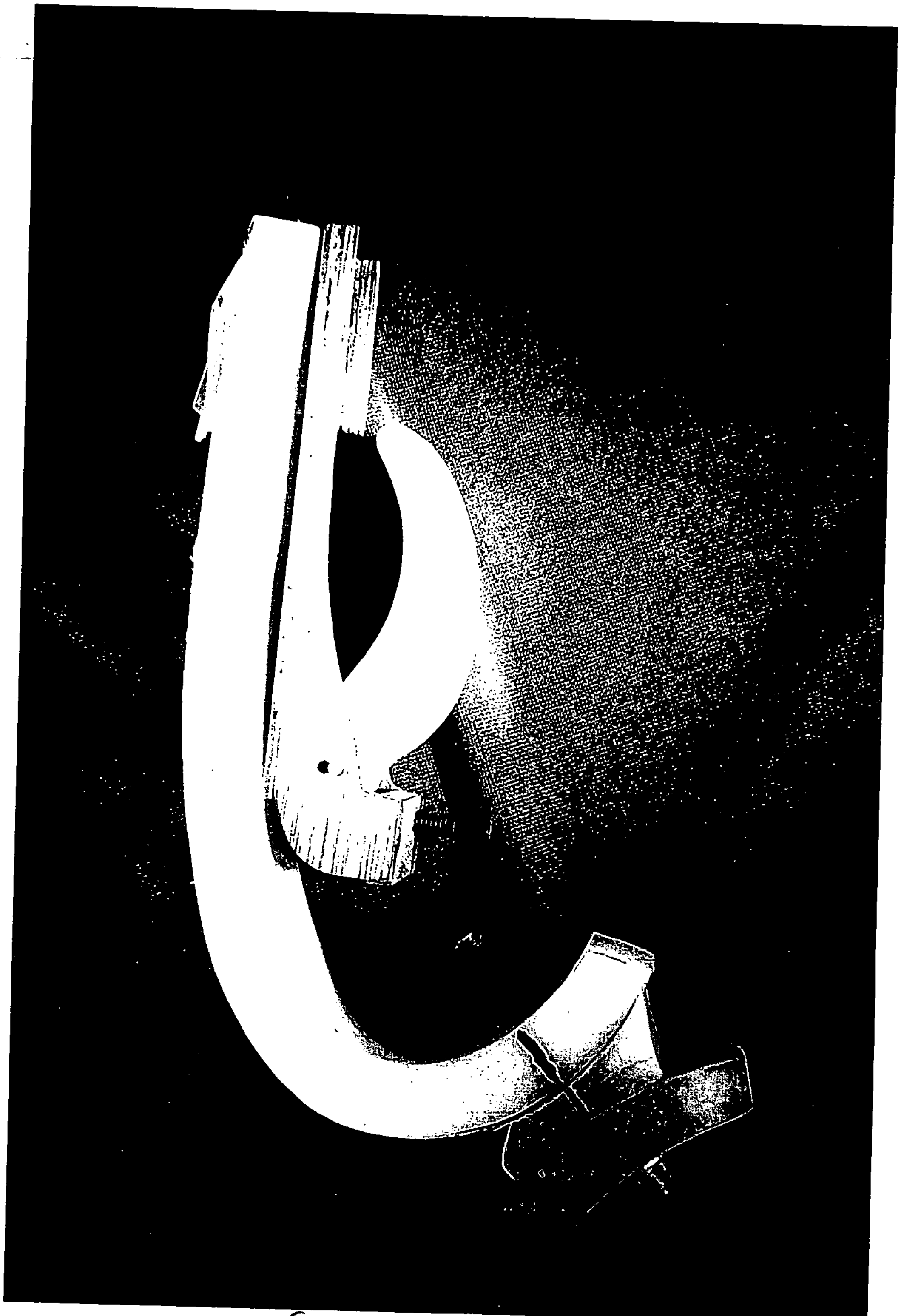


FIG 23

Pneumatic or Hyraulic - ELECTRIC

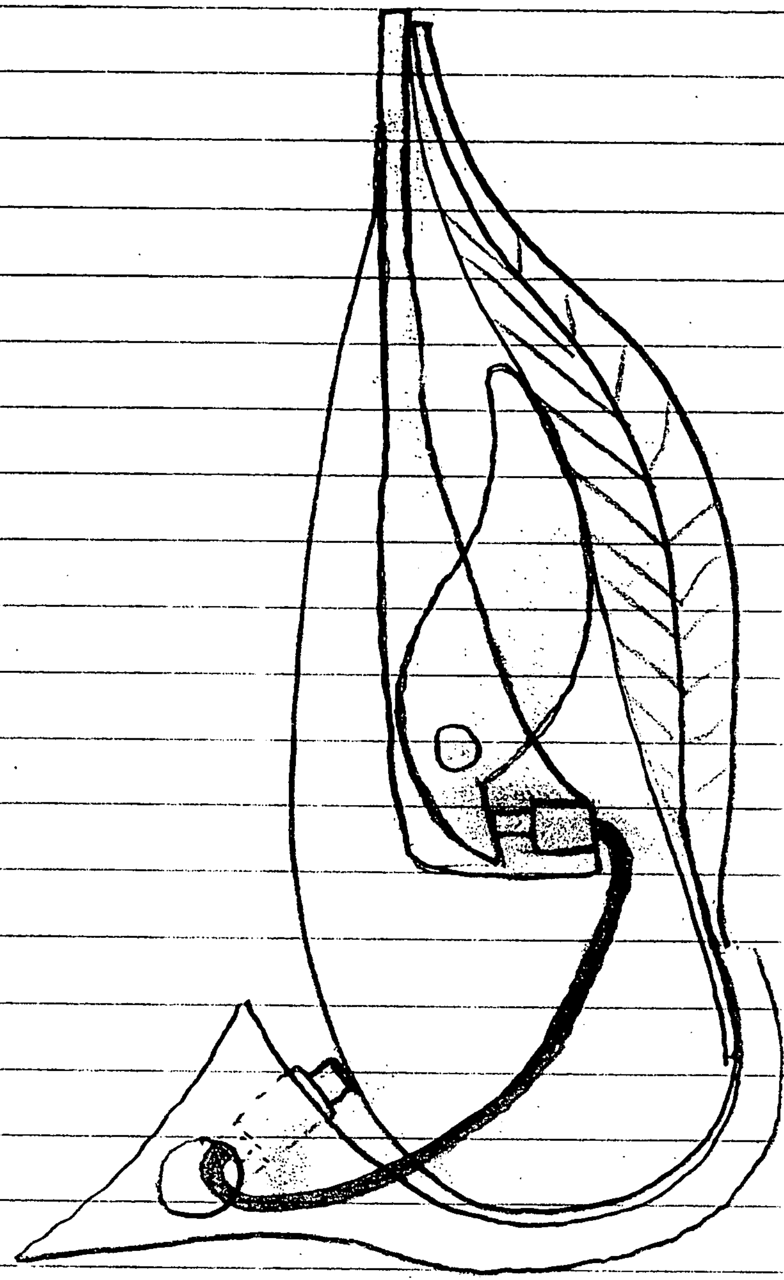


FIGURE 24

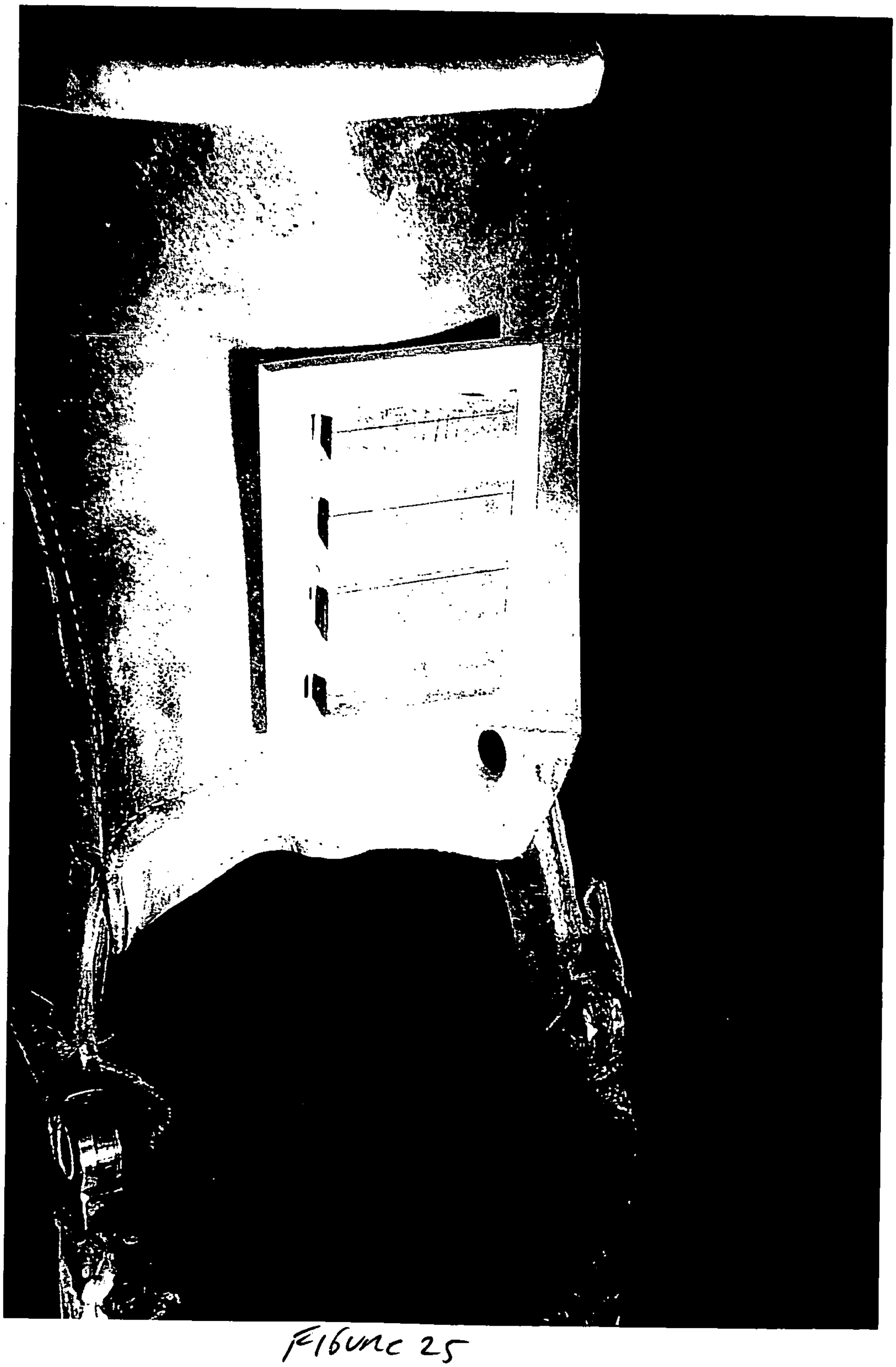


Figure 25

FIGURE 26

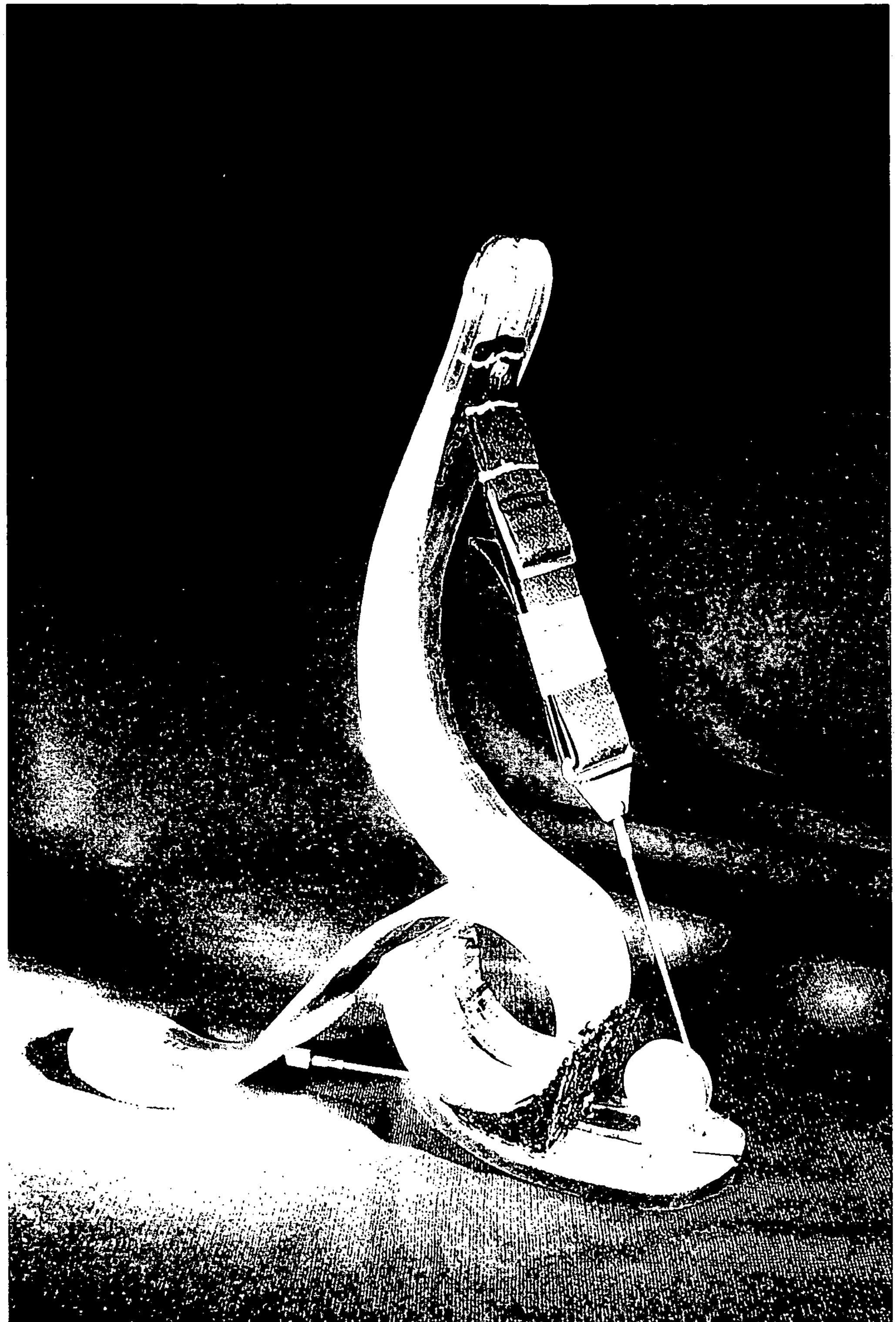


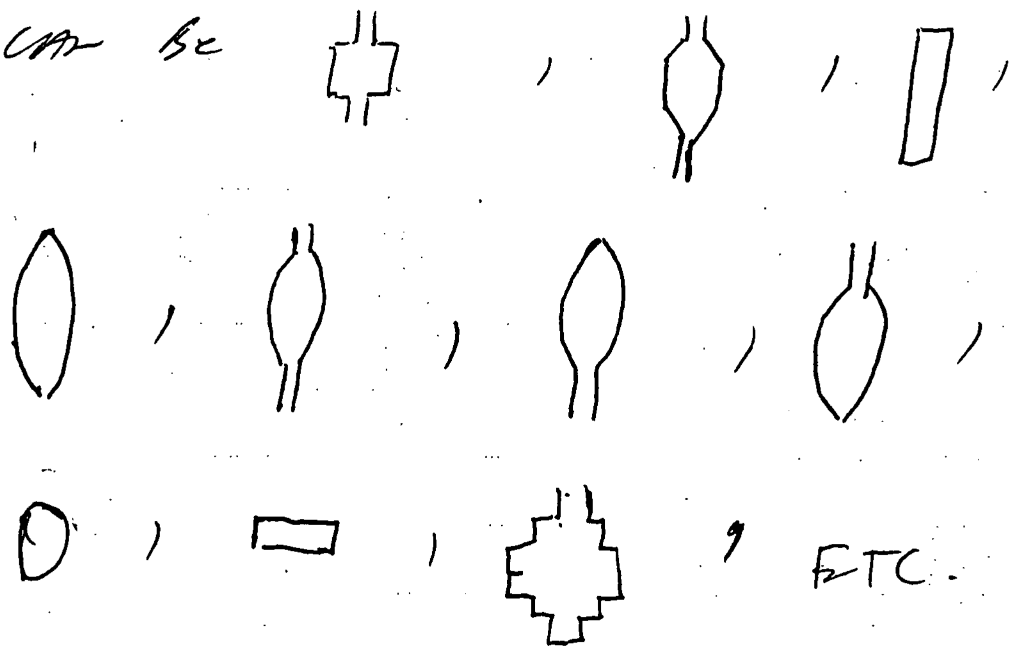
FIG 27

Fig 28

OUR PROSTHETIC MUSCLE CAN BE SHAPED CROSSECTIONALLY AS A: ▭ RECTANGULAR, □ SQUARE, OBLONG, - FLAT, , , ○ ROUND, △ TRIANGULAR, QUADRANGULAR, OCT, PENT, ETC.  + TUBULAR  IN THE ABOVE SHAPES FOR EXAMPLE .

FIGURE A

THE ELONGATED SHAPES CAN BE

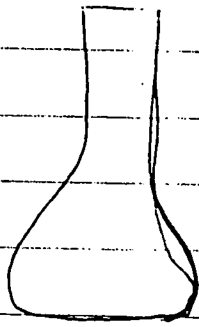


ETC.

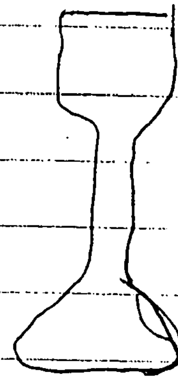
FIGURE B

222

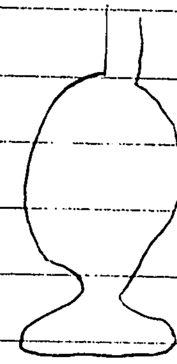
TAB
#2



M

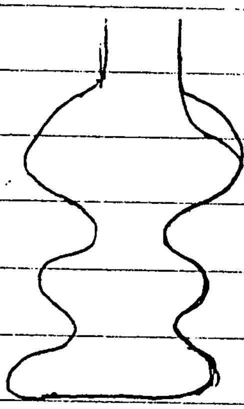


N

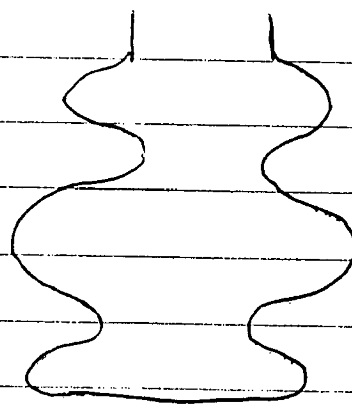


O

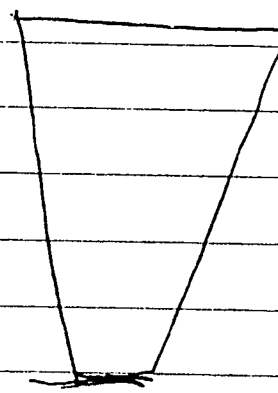
(22) In CUTOUTS ~~[illegible]~~ FOR A SINGLE LEAFSPRING CAN BE SINGLE + OR MULTISHAPED. WITH EACH CONFIGURATING / CREATING DIFFERENT SPRING RATES
OF CUTOUTS



P



Q

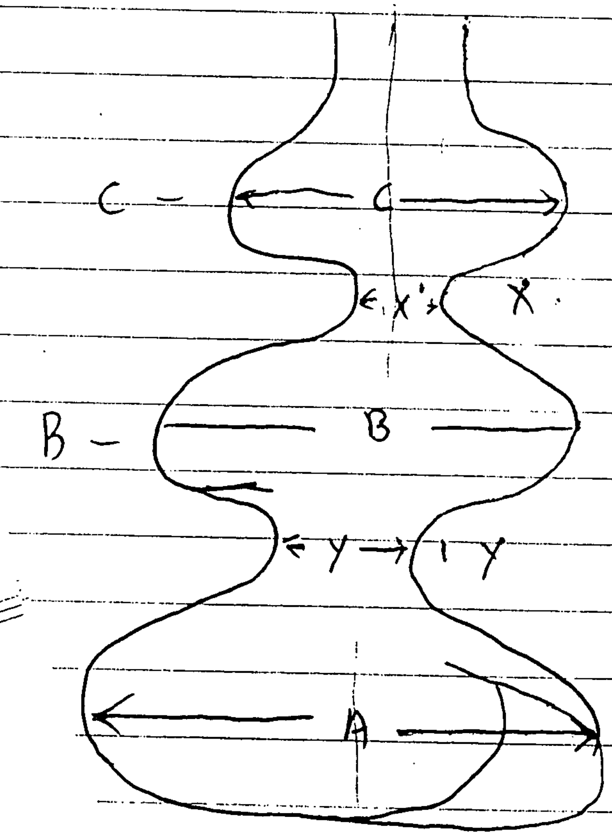


Q_B

OUR LEAFSPRINGS CAN HAVE CURVILINEAR ~~[illegible]~~ SIDES + OR STRAIGHT SIDES

OUR LEAFSPRINGS CAN ~~HAVE~~ HAVE SYMETRY + OR ASYMETRICAL FORM. OUR LEAFSPRING CAN HAVE VARIED SPRINGS RATES WITHIN THE MONOLITHIC ~~[illegible]~~ FORMING, WHEREIN THE SPRING RATE CHANGE SOFTER + OR FIRMER DEPENDING ON THE CURVILINEAR FORMS.

FOR EXAMPLE



R

230

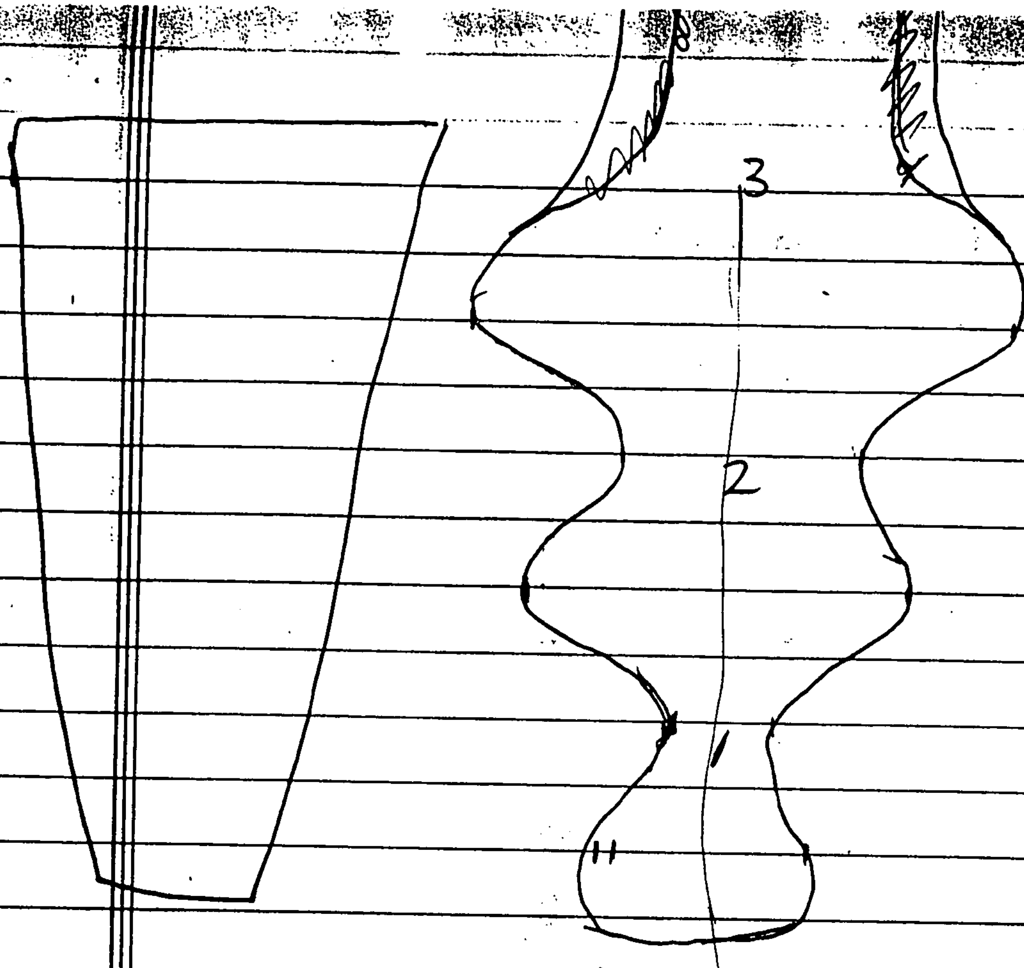


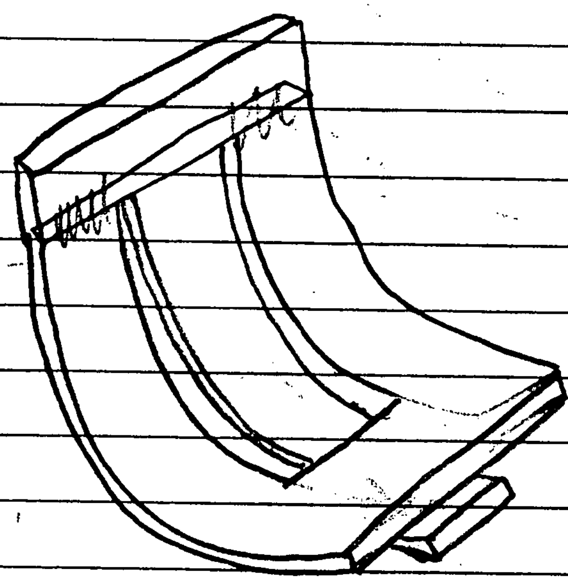
FIG 5

~~VOLD~~ WOULD BE UTILIZED GIVEN US

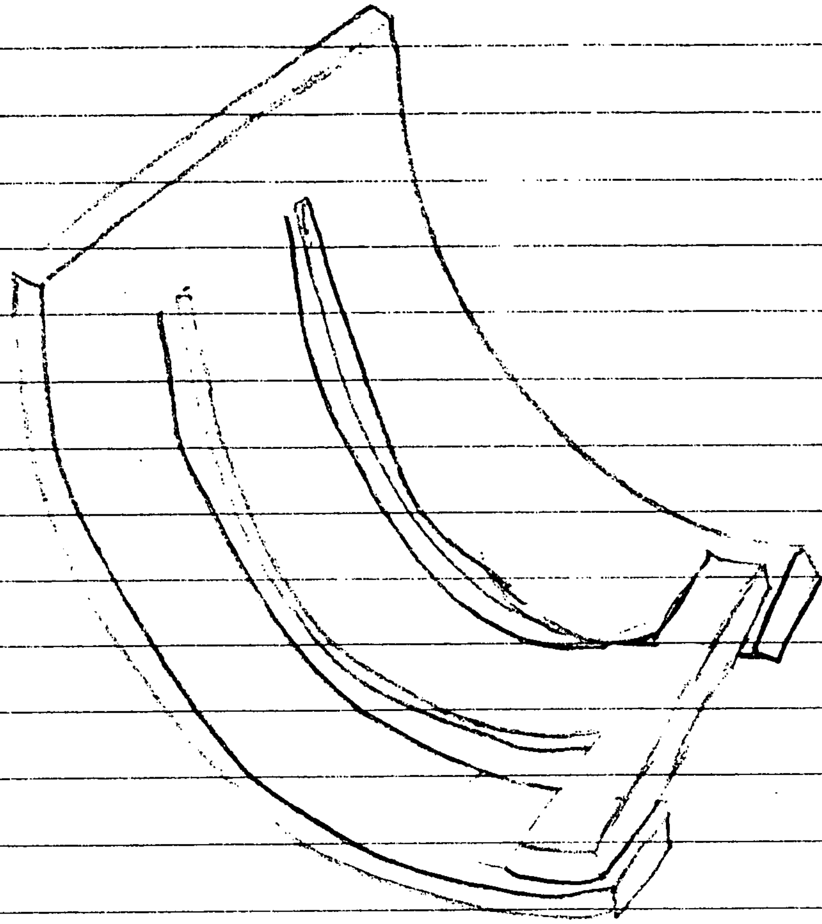
A MECHANICAL STRUCTURE THAT

RAMPS UP ITS SPRING RATE ~~TO~~
PROPORTIONAL TO ITS FORCE LOAD.
~~AS DETERMINED BY ITS LOAD.~~

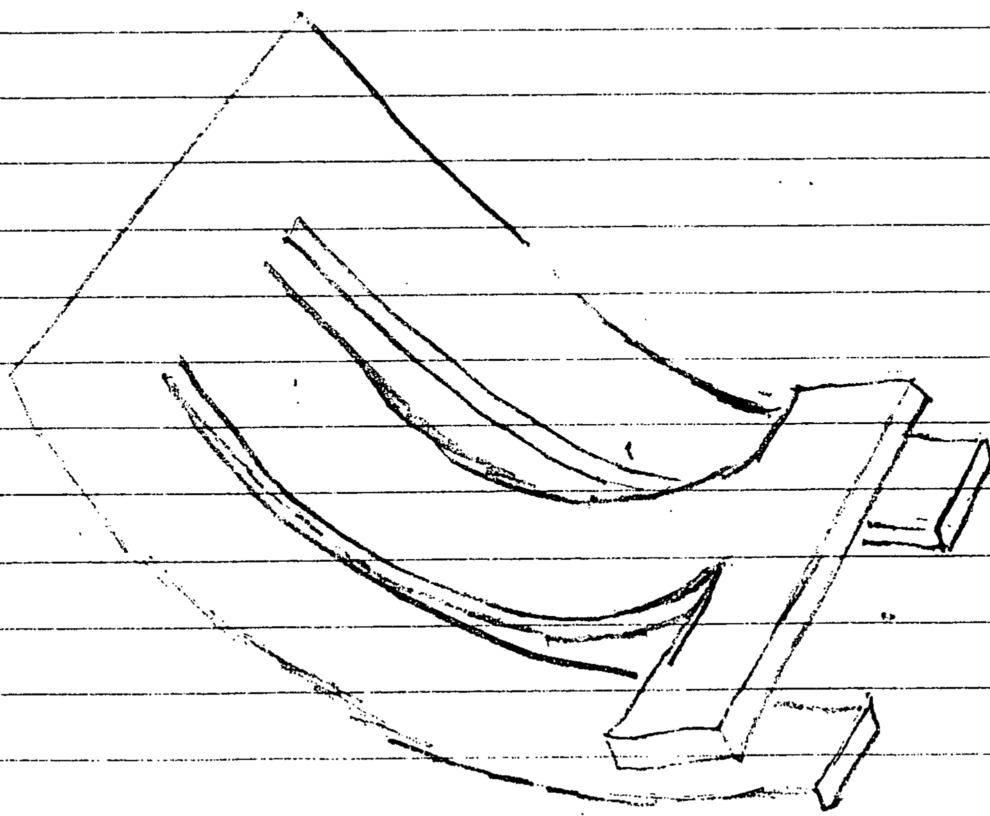
ANOTHER ~~[illegible]~~ VARIED EMBODIMENT WOULD BE TO HAVE A LEAFSPRING THAT HAS A RAISED MIDDLE SECTION THAT WOULD ~~[illegible]~~ ENGAGE AS FORCE LOADING GOES UP. FOR EXAMPLE T_{1-4}



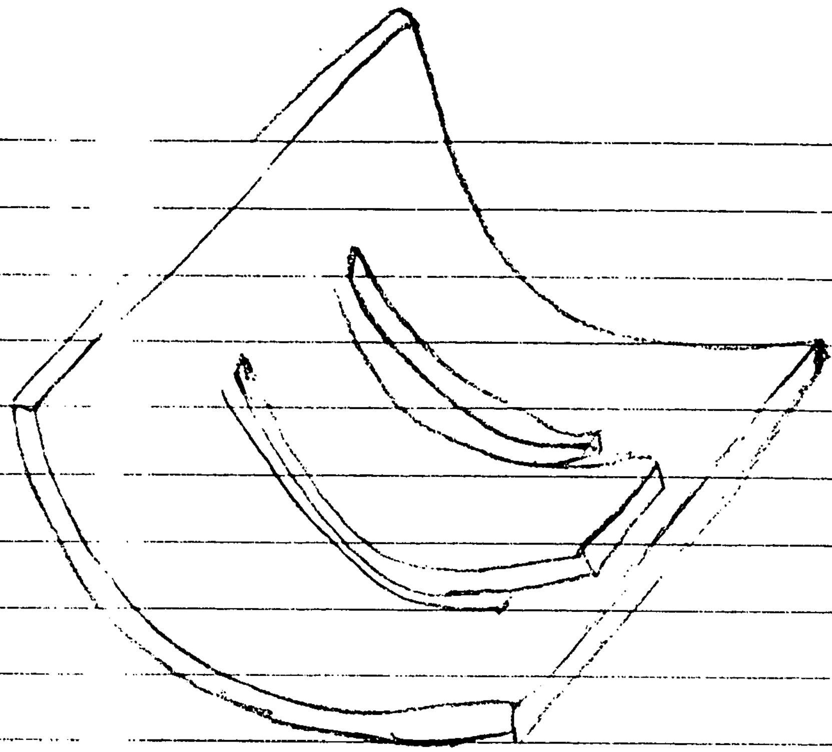
T_1



T2



T3



T4

THIS PARTICULAR LEAFSPRING DESIGN DOES NOT HAVE TO BE ~~RECTILINEAR~~ RECTILINEAR IN FORM BUT COULD BE CURVILINEAR IN FORM COMBINING BOTH CURVILINEAR + OR ~~RECTILINEAR~~ RECTILINEAR FORMS. ANY BODY SKILLED IN THE ART WOULD KNOW THAT OUR BASIC DESIGN PRINCIPLES COULD BE COMBINED